REDCap eDocs Module
Validation Summary Report

University of Vanderbilt
Medical Center

Document Version: 1.0

Document Date: 31-Mar-2020

Signature Page

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

Signature: Gaurav Kumar (Mar 31, 2020)
Email: gkumar@jafconsulting.com
Title: Validation Lead
Company: JAF Consulting, Inc.

Gaurav Kumar Validation Lead, JAF Consulting, Inc

Reviewed and Approved by:

I have reviewed the contents of this document and accept and approve of the provisions as stated herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

Signature: Colleen E. Lawrence (Mar 31, 2020)
Email: colleen.lawrence@vumc.org
Title: Manager, Translational Research
Company: Vanderbilt University Medical Center

Colleen Lawrence, System Owner

Signature:
Email: jfranchetti@jafconsulting.com
Title: President
Company: JAF Consulting Inc

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Signature: Rob Taylor (Mar 31, 2020)
Email: rob.taylor@vumc.org
Title: Manager of App Development
Company: VUMC

Rob Taylor, Technical Owner, VUMC

Signature: Paul A. Harris (Mar 31, 2020)
Email: paul.a.harris@vumc.org
Title: Director, Office of Research Informatics
Company: Vanderbilt University Medical Center

Paul Harris, Management, VUMC

Revision History

Date	Version	Description
31-Mar 2020	1.0	Initial Release

Table of Contents

1 Introduction

1.1 Overview

Vanderbilt University developed an eDocs module within REDCap application designed to upload 21 CFR part 11 compliant electronic file upload feature associated with a study id. The final, approved study ids are then stored in an electronic vault, where it can be retained and viewed for the required retention period.

1.2 Objective

This Validation Summary Report (VSR) serves as the summary of the validation execution effort providing an understanding of the inventory of documents created during the validation effort, Team Roles involved in the effort, any deviations encountered during testing and any requirements deferred from the planned release.

2 Validation Deliverables and Documentation

2.1 Table of Validation Deliverables

Document/Deliverable	Version	Completion
REDCap eDocs Validation Master Plan	1.0	20 Feb 2020
REDCap eDocs Module User Requirements Specification	1.0	16 Feb 2020
REDCap eDocs IQ Test Protocol	1.0	17 Feb 2020
REDCap eDocs PQ Test Protocol	1.0	17 Feb 2020
REDCap eDocs IQ Test Protocol Execution	1.0	27-Mar-2020
REDCap eDocs PQ Test Protocol Execution	1.0	27-Mar-2020
REDCap eDocs Validation Summary Report	1.0	This Document
REDCAP eDocs Module Requirements Traceability Matrix	1.0	27 Mar 2020
SOPs/Release Training	1.0	31-Mar-2020

3 Team Roles

The following table outlines the personnel who played roles with the REDCap eDocs validation effort.

Name	Role	Dates on Validation project
Gaurav Kumar	Validation Lead	Jan 2020 – Present
Joe Franchetti	Quality Assurance Representative	Jan 2020 – Present
Rob Taylor	IT Representative, SME	Jan 2020 – Present
Colleen Lawrence	System Owner	Jan 2020 – Present
Paul Harris	System Management	Jan 2020 – Present

4 Validation Test Execution Summary

4.1 Methodology

The methodology used for the validation of regulated computer systems is outlined in the approved Validation Plan.

The Validation deliverables and documentation based on the validation methodology are outlined in the following subsections:

4.1.1 User Requirement Documents

A document titled "REDCap eDocs System Requirements Specification - Final v01" was created and approved on 16-Feb-2020. This document was used in the creation of the Requirements Traceability Matrix (RTM).

4.1.2 Requirements Traceability Matrix

The RTM was approved on 27-Mar-2020. This document will provide traceability between the Requirements and Testing.

4.1.3 Qualification Activities

There was an IQ Plan Developed and approved pre-execution. The document is titled REDCap eDocs IQ Test Protocol and Test Scripts - Final v01.This IQ was a verification of the installation of the REDCap instance and was not a prospective installation qualification.

There was an initial Performance Qualification Plan and test scripts developed "REDCap eDocs PQ Test Protocol and Test Scripts - Final v01". The executed version of the protocol was completed on 17-Feb-2020.

The test scripts from the *IQ and PQ protocols were* and testing was completed following the methodology and qualification instructions of the Validation Plan document. Executed Test Scripts are part of the Validation evidence. Supporting evidence (e.g., reference documents, screen printouts, graphs and reports) are attached to each of the representative test scripts.

4.1.3.1 Execution of the Test Plans and Evaluation of Test Results

A printed copy of the pdf version of the approved Test Scripts were used as the execution copy for both IQ and PQ. All test results will be documented, reviewed, and evaluated according to the acceptance criteria. The completed validation test result pages, and supporting documentation, were collected during execution of the plan and are attached and labeled accordingly. A summary of the attachments to the test script is contained in Attachment #5.

4.1.3.2 Operational SOP

The procedure is in Draft state and will be used as a guideline in the operation activities for the eDocs process. The procedure applies to the following eDocs business processes.

4.1.3.3 Administration SOP

The procedure is in Draft state and will be used as a guideline in the Administration for the activities for the eDocs process. The procedure applies to the following eDocs business processes.

4.1.3.4 Passwords from VUMC IT department
For Vanderbilt employees, they use a VUnetID, which is provisioned by the VUMC IT department. For external users (non-Vanderbilt employees), the password is provisioned by REDCap internally. Password aging – all passwords are required to be reset every 365 days (both Vanderbilt and non-Vanderbilt users)

4.2 Deviation

There were 4 deviations that occurred during the execution of the Test Protocols and all were successfully reconciled (see below for details). Execution of the test protocols verified the system will completely and accurately operate and perform according to predetermined specifications within the user environment.

The following table describes number of deviations, Types of deviations which were summarized with their impact and criticality and finally disposition of the deviations.

The Deviation log is attached to this Summary in Attachment #3

The individual deviations are attached as part of this Summary in Attachment #4

Deviation Number	Summary of Deviation	Disposition
eDocs-IQ-001	Hardware specifications listed in the expected results section of the IQ document didn't match actual specifications of the REDCap webserver. Installed Specifications were meeting and / or exceeding the specifications listed in the expected results.	Closed
eDocs-I/PQ-002	IQ and PQ document were scheduled to be executed concurrently. No validation impact as this is a retrospective validation of the eDocs module.	Closed
eDocs-I/PQ-003	Testing performed with one user role. Protocol generation errors on steps 32 and 33.	Closed
eDocs-I/PQ-004	Data backup and restore functionality was not tested in the PQ protocol as this test has been successfully completed and verified in the IQ test protocol.	Closed

4.3 Deferrals

No issues identified during the testing were deferred for a future release.

5 Personnel Qualifications / Training

Each individual participating in the execution of the computer validation effort was qualified to perform their associated validation task. The Consulting Firm of JAF Consulting, Inc, was utilized as the contractor in this validation effort. Gaurav Kumar was the lead validation consultant and test executor. Joseph Franchetti, Managing Consultant of JAF Consulting was participating as Quality Reviewer. Both of their resume is attached to this report in Attachment #2.

All users to the system were trained in the SOPs and / or Work Instructions. This training documentation will be maintained as part of the individual users Training Dossier / file.

6 Signature Identification Log

The signature identification log has identified all the individuals, who signed or initialed any validation page executed under the Validation plan. The identifications were recorded on the Original Approved Signature Identification log of the Validation Plan and the final is attached to this Summary in Attachment #1.

7 Validation Package/System Release

The Validation Package consists of approved and executed plans, test scripts and test results, reports and supporting documentation as defined in the Validation Master Plan. All approved hardcopy Validation documents will be scanned and kept in a controlled access area.

A Quality Assurance Representative will review the full Validation package after completion to assure that all validation activities have been successfully completed and that documented evidence exists to substantiate the declaration that the Validation has been completed.

Release of the system will be documented and communicated to the System Owner and System Management, who will make sure that users are appropriately trained on the use of the system prior to gaining access and any necessary procedures for the new system documented and released as effective.

8 Validation Conclusion

The planned validation activities have successfully been executed according to REDCap eDocs Validation Plan as referenced above and the REDCap eDocs Module is recommended for release by the System Owner.

The system status will become validated upon final approval of this Validation Summary Report by the System Owner and Quality Assurance.

All Phases of the Validation defined in the REDCap eDocs Validation Plan have been performed, and test results were as expected. The REDCap eDocs module is acceptable for use in the production environment.

8.1 System Restriction / Limitations

There are no restrictions in the use of the eDocs Module.

8.2 Recommendations, Regulatory and Quality Statements

Based on a review of the validation documents and test executions, the REDCap eDocs implementation has successfully met the requirements for Computerized System Validation.

Signed acceptance of this document and all supporting relevant documentation will denote that the System can be placed in production for regulated activities except for the restrictions defined in section 8.1 of this report.

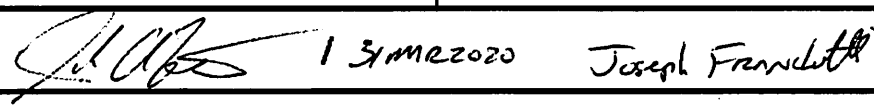
9 Regulatory References

List of regulations that will need to be considered or met related to the system:

- HIPAA (Health Insurance Portability and Accountability Act of 1996)
- FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997

Appendix 4: Validation Signature Log

All Participants in this validation effort must complete the following information:

Name (Printed)	Title / Responsibility	Signature	Initials	Date
Gaurav Kumar	Validation Representative, JAF Consulting Inc.		gk	31 MAR 20
Reviewed By/ Date				

Page 1 of 1

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SUMMARY OF QUALIFICATIONS AND EXPERIENCE:

Over Thirty years of progressive experience in addressing the Pharmaceutical, Life Science, Medical Device and Healthcare Industries needs in the area of Regulatory Compliance. Assists organizations in providing pragmatic guidance in Regulatory Compliance, Quality Assurance, Information Technology, and Data Management that provide unique solutions to technical problems based on current industry trends and regulatory expectations. Practical, results oriented individual, able to work effectively with a wide variety of people and has proven ability to effectively lead / influence cross-functional teams and to interact with key stakeholders at the regulatory / executive levels. Able to build internal and external networks and creates and sustains excellent working relationships with regulatory agency personnel, colleagues, clients, and external vendors. Able to manage multiple tasks while maintaining established deadlines and overall project perspective. Possess excellent oral and written communication and interpersonal skills.

Participated in many industry groups in the publication of multiple working guidance on system implementation and regulatory compliance.

Experience in: Auditing and Assessments; HITECH / HIPAA Privacy and Security, Vendor Qualification, Corrective Action / Preventative Action (CAPA); Consent Decree and Warning Letter resolution; Project Management; Quality Systems Implementation (GCP, GLP, GMP); Pharmacovigilance and Drug Safety (US / EU No 1235/2010); Instructional Design; Training; Vendor / Supplier and Compliance Audits; Biosafety Level 2, BSL3,and BSL4; Computer System Validation; US & International Regulatory Expectation (cGLP's, cGMP's, & cGCP's, ISO Standards, Sarbanes-Oxley (SOX), 21 CFR Part 11, European Union / EC / EMA, Japanese Ministry of Health Labor and Welfare); Good Distribution Practices (GDP), Information Technology; Quality Assurance (QA); Quality Control (QC); Data Management; Laboratory Robotics; Laboratory Operations and Analysis(GxP); Drug Discovery; Informatics; and Standard Operating Procedures and Documentation.

SELECTED ACCOMPLISHMENTS:

Auditing & Assessment

- Acting as Lead Auditor for pharmaceutical company client, conducted multiple GMP audits for API Manufactures in China and South Korea. Audit focus was to evaluate pertinent processes, procedures, and facilities applicable to GMP Manufacturing of API material. An assessment of the Quality Management System required for GMP compliance was also conducted to ensure it is effective as it relates to Data Integrity Practices. Additionally, we assessed if the if the laboratories are able to perform the QC testing in compliance with the requirements of the FDA GMP regulations and guidance.
- For multiple Pharmaceutical Clients, acting as Lead Auditor, performed numerous Active Pharmaceutical Ingredient manufacturer audits in US, India, and EU. Performed audits against FDA and EU regulations as well as ISO Standards. The compliance audits assessed the organization's manufacturing processes against current regulatory expectations along with company policies and procedures. Reviewed and assessed complete equipment and computer validation documentation, standard operating procedures, and organizational policies to document the gaps in processes. Recommended policy change, procedure revisions and, additional validation to bring the organization into regulatory and corporate compliance.
- As Lead Auditor, performed numerous Supply Chain (Cold-Chain) audits to assess Good Distribution Practices by a number of 3PL and Pharmaceutical organizations. Reviewed and assessed documentation, standard operating procedures and organizational policies to document the compliance to the current GMP and GDP expectations. Also participated in remediation of findings for a number of clients.

Auditing & Assessment

- Acting as Lead Auditor and Assessor, conducted multiple HIPAA / HITRUST audits for healthcare facilities. Assisted with remediation and risk management efforts by implementing control programs for data security, HIPAA / HITRUST compliance, and protected personnel information. Help provide overall IT governance that targets IT alignment and strategic needs and requirements of clients. Secure enterprise information by designing, and implementing IT security controls, safeguards, policies, and procedures. Plan information security awareness programs for security audits.
- Acting as Lead Assessor, conduct GDPR assessment, assess data workflows and data mapping, provide input on controls to comply with the GDPR regulation. Provide training and consultation on GDPR.
- Acting as Lead Auditor, conducted multiple Data Integrity and Data Quality Audits for major pharmaceutical clients, Contract Research Organizations as well as Contract Manufacturing Organizations. Assisted in remediation efforts to bring organizations into compliance.
- Acting as a Clinical Quality Assurance Auditor, for international pharmaceutical organization, performed numerous Phase III Investigator compliance audits to assess adherence to clinical protocol, company procedures and current regulatory expectations.
- Acting as Clinical Auditor conducted Good Clinical Practice Audits: qualification site (Full Service CRO and LAB), investigator site, Trial Master File (TMF and eTMF), vendor assessments and facility audits for major pharmaceutical client. Assisted Vice President of Quality in establishing clinical quality assurance standard operating procedures and standardized reporting tools. Provided Good Clinical Practices, Good Documentation Practices, Auditing Techniques and other topics related to Quality Assurance. Working knowledge of clinical trial processes, EMA, EU Directives, ICH guidelines, and FDA regulations.
- Performed numerous CRO compliance audits to assess clinical trial management databases and other systems against current regulatory expectations along with company compliance policies. Reviewed and assessed documentation, standard operating procedures and organizational policies to document the compliance of current protocol.
- For multiple Pharmaceutical Clients, acting as Project Lead for the establishment of a sustainable and risk based Information Technology Vendor Audit and Qualification Program. The team provided a structure to support the existing vendor base, as well as the future state of vendors. The process focused on the overall and inherent risk of IT vendors who are providing products (hardware or software) or services (Consulting, SW Development, SaaS, PaaS, IaaS) to the organization. For existing vendors, the risk determination was based on what the Regulatory, Technical, and Business risk the products or services contributed to the current operations. Vendor Qualification options for existing included: An On-site audit (High Risk), Qualification by checklist (Medium Risk), Qualification by past performance (Low Risk), No audit or checklist (Minimal Impact on process). The processes also included the monitoring and re-qualification of vendors and how to categorize and track audit observations.
- Participated as Lead Auditor on audits of numerous Dietary Supplement Manufactures to identify deficiencies through review and observation, and to determine and establish appropriate corrective actions to ensure FDA compliance. These audits focus on elements of the manufacturing, packaging, labeling, and storing of dietary supplements as outlined in 21 CFR Part 111. The audits provide reasonable assurance that documented and controlled processes are in place so that products meet their established specification for quality, including identity, purity, strength and composition. Once corrective actions have been agreed, managed the remediation of the plans activities.
- Conducted evaluations of organizations Computerized Systems to with regard to Sarbanes-Oxley and FDA Requirements and COBIT Standards. Evaluations consisted of review and analyses of existing computer systems documentation to ensure compliance to internal standards and applicable SOX and FDA regulations. Mapped COBIT controls to SOX and FDA requirements. Developed corrective action plan and managed the remediation of the plans activities.
- Developed and implemented vendor assessment programs for several pharmaceutical companies. Developed assessment criteria for auditing and evaluation of current and potential suppliers.

Auditing & Assessment

- Conducted numerous validation and vendor audits. Evaluations consisted of review and analyses of existing computer systems documentation to ensure compliance to internal standards and applicable FDA regulations. Recommendations provided clients with an independent assessment of their exposure to regulatory action and provided the basis for development and establishment of corrective action plans.
- Acting as an Industry Principal on the project team, was responsible for the successful delivery of the project. Project involved a Data Quality Audit is to develop a detailed, baseline assessment of the current level of data quality within USP's transactional environments (Access Database, Home grown application with Oracle database backend, and Oracle's E-Business Suite (EBS) Enterprise Resource Planning (ERP) application) for use in developing a formal Master Data Management program. Concentration was placed on customer-type and item-type transactional data.

  Responsible for leading the Business User Working Sessions with the Project Manager, Documenting the Business Processes and findings, documenting the data requirements, creating the value proposition presentation for the implementation of an Master Data Management (MDM) Program (Data Quality, Governance, Enrichment, Compliance and Integration). Contributed to the evaluation of multiple MDM Tool Vendors to present recommendations and next steps for the MDM implementation.

  As part of the analysis of the data, determined that there were significant consistency and conformity issues with customer type data in all of the systems. Also identified that there were no programmatic processes to force correct data entry, or any pick list generation to aid in the correct information being entered. The Business Process findings indicate that users needed more training in the use of EBS as well as understand the search process to identify existing customers in the system, as well as the need to document existing process to facilitate the consistent application of the process to the data.
- Performed numerous validation compliance audits to assess systems against current regulatory expectations along with company compliance policies. Reviewed and assessed complete validation documentation, standard operating procedures and organizational policies to document the gaps in processes and validation effort. Recommended policy change, procedure revisions and, additional testing to bring the systems into regulatory and corporate compliance.
- Conducted compliance and vendor audits on numerous Information Technology Departments with multiple platforms (Linux, Windows, VMWare, NT, 2000, VAX, UNIX) and many types of corporate wide applications (Oracle, LIMS, EDM, Home Grown).
- Performed compliance audits to assess organizational compliance against current regulatory expectations and company policies and guidelines. Reviewed, revised, recommended and assessed documentation, standard operating procedures, and organizational policies to make consistent with current approach and industry expectation.

Network and Data Center Qualification

- Performed multiple Network and Data Center Qualification projects for Pharmaceutical and Contract Research Organization Clients to support Validated systems in regulated environments. Lead a technical team through the qualification process which involved defining specifications and requirements, documenting as built configuration of a networks, developing standard operating procedures, and Disaster Recovery / Business Continuity. Process used risk-based testing for the requirements and specifications. Activities followed a combination of IVT and GAMP guidance to complete the successful projects.

Compliance & Training Activities

- As Acting Director of Quality Assurance for a Functional Service Provider, I developed their quality system. The Quality System developed entails a Quality Manual which details all aspects of the Quality procedures for the Administrative, Operational and Information Technology areas of the organization. Developed processes for SOPs, CAPA, Internal Audits, Record Retention, Vendor Management, Change Control, and Computer Validation. The quality systems for the organization must comply with Good Clinical Practice regulations. Assisted in developing Clinical Study Protocol, Informed Consent, Investigator Brochure, Site Initiation / Closeout, monitoring as well as other Clinical SOPs needed for study conduct. This quality system has withstood a number of vendor audits and has had only minimal observations which are placed and resolved through the CAPA process. The internal audit process has identified items which have been placed into the CAPA process and have been, or continue to be resolved.
- Acting as GCP Clinical Quality Assurance Consultant to provide expertise on Operating Procedure direction, Vendor Management process and overall Vendor and Clinical Site Oversight and Auditing.
- Developed and Delivered training programs to organizations utilizing webinars for 21 CFR Part 111 (Dietary Supplements GMP Regulation) and e-Liquid Manufacturing Standards. Assisted organizations in developing Quality Management Systems to comply with Dietary Supplement GMP regulations and e-Liquid Manufacturing Standards.
- Instructional Designer: Work closely with industry experts and colleagues to develop highly interactive, two-day training course in Regulatory Compliance as it relates to Good Clinical Practices and Computer System Validation. Provided team with leadership and instructional design guidance throughout the development process.
- For an international Pharmaceutical Client, developed training materials for Computer Validation Training, including Instructor-led Training materials. Synthesized information from subject matter experts and software developers, analyzed business process and audiences, and developed business process flows. Participated in Train the Trainer and Quality Coach training sessions.
- Functioning in the role of Quality Assurance Director developed a quality system for a reverse logistics organization that handles recalled, expired, and trade return pharmaceutical product. The Quality System developed entails a Quality Manual which details all aspects of the Quality procedures for the Administrative, Operational and Information Technology areas of the organization. Developed processes for SOPs, CAPA, Internal Audits, Record Retention, Software Development Lifecycle, Change Control, and Computer Validation. The quality systems for the organization must comply with FDA, EPA, DEA, and OSHA regulations. This quality system has withstood a number of vendor audits and has had only minimal observations which are placed and resolved through the CAPA process. The internal audit process has identified items which have been placed into the CAPA process and have been, or continue to be resolved.
- Collaborated with key stakeholders (Sr Management / Executives) and participants (Staff) to develop a training and compliance strategies that takes into account the organizational business needs and regulatory expectations.
- Delivered training program to organization utilizing self-instructed web based and traditional training and educational formats for Computer Validation and Vendor Audit workshops.
- Designed and implemented computer systems validation training courses for both public and company specific training programs. These courses covered the complete integration of validation concepts and requirements during the System Development Life Cycle and addressed product, process and business support software systems. The training was for new corporate associates and was their introduction to the regulations that the Pharmaceutical industry must follow.

Project Management & Project Participant

- Lead and direct project teams through full System Life Cycle from RFP to pre-purchase to project initiation to use and maintenance phases by applying effective project management methodologies and control techniques.
- Conceptualize, write, review, and evaluate project plans and objectives.
- Document and / or Re-Engineer existing process.
- Negotiate with clients, colleagues, and partners.
- Communicate project status, milestones, and issues.
- As a project team member and Subject Matter Expert, evaluated biopharmaceutical manufacturer's sample tracking, labeling and analysis to identify and implement more efficient process, technologies and hardware to manage intermediate and final product analysis. Implemented bar code system to interface JDE and Labware LIMS to provide compliant labeling and more efficient sample analysis.
- Developed Quality Management System for organization to support administrative, operational, and information technology processes including CAPA process to address best practices to maintain regulatory compliance (GCP, GLP, GMP).
- As a Project Manager for a multi-site global pharmaceutical company, performed an extensive analysis of critical business needs, and functional and technical requirements for the development of a user requirements specification that was used to evaluated LIMS suppliers as part of a Request for Proposal (RFP) process. Participated in the selection and procurement of the SQL*LIMS Software. Validated the LIMS based on the refined user and functional requirements, and technical specification documentation. LIMS was Oracle database web enabled application. Included Modules on: Training and Analyst Certification, Portal for External Stakeholders, Barcode Integration and Drug Stability Management and Analytics.
- As a Project Manager for a global pharmaceutical company, prepared Request for Proposal (RFP), evaluated RFP responses and lead client team Vendor Evaluations, provided negotiation points for the purchase of an Enterprise Laboratory Information Management System (Selected LabWare Enterprise LIMS Application). Managed Vendor / Partner throughout the implementation process by implementing a clear communication process and clear quality procedures which allowed the vendor to fully understand their role and expectations. This was also accomplished by developing clear and concise technical documentation. Also managed complete resourcing and budget for the project team of 10 Contractors.
- Planned and executed entire validation lifecycle for clinical drug safety and adverse event reporting systems, legacy and new laboratory systems, and document management archive database system. These efforts included consultation with client validation, quality assurance, information management, and user representatives leading to the development of, and adherence to, user and functional requirements, and project master plans used to direct all validation activities. Assessment of Pharmacovigilance processes and procedures against current regulatory expectations to provide revision of processes and definition of systems requirements. Developed and executed qualification protocols, test scripts and reports (installation, operation, performance, and vendor) that comprised the overall validation packages. Application was Oracle database backend.
- As a Project Manager for a global pharmaceutical company implemented a business intelligence data warehouse application that enabled access to drug safety evaluation and pharmaceutical candidate optimization data from numerous validated systems. The access to this data enabled the study directors and scientists the ability to analyze many different sets of data that were not able to be compared and analyzed in the past. This will lead to better safety information and more practical study design.

  This was accomplished by developing clear and concise technical and user documentation. Also managed complete resourcing and budget for the project team of 10 Contractors.

Project Management & Project Participant

- As a Project Manager, performed an analysis of critical business needs, and functional and technical requirements for the development of a user requirements specification that was used for the validation of internally developed pharmaceutical returns management system. System also processed returns for recalled pharmaceutical products. Also developed validation deliverable for implementation of Returns Management System: Validation Plan, Requirements Specification (Functional, User, System, and Configuration), Requirements Traceability Matrix, Installation / Operational Qualification Protocol and Test Cases, User Acceptance Test Protocol and Test Cases, Standard Operating Procedures.
- As a Project Manager for a pharmaceutical company prepared User Requirements documentation and project plan for the purchase and implementation of a clinical laboratory sample management system. This system would interact with clinical trial management systems as well as electronic data capture process to fully integrate the clinical process. A request for proposal (RFP) was drafted and vendor evaluations were conducted. The application is in the process of being implemented in-house for the company.
- As a Subject Matter Expert - Developed Validation deliverables (Validation Plan, Requirements Specification, Test Plan and Test Scripts) for the Implementation and Validation of Adobe Signatures.
- Managed site wide computer system validation compliance project for major global pharmaceutical client with a diverse senior management project team. Project entailed remediation of Laboratory and Manufacturing Equipment Computer Systems, Building Automation Systems, and 21 CFR Part 11. The Project also included harmonization of site procedures in Computer System Validation, Change Control, 21 CFR Part 11 Policy, and IT infrastructure. Responsibilities included but not limited to Documentation Preparation & Review and Project Planning & Updates.
- Planned and executed entire validation lifecycle for clinical drug safety and adverse event reporting systems, legacy and new laboratory systems, and document management archive database system. These efforts included consultation with client validation, quality assurance, information management, and user representatives leading to the development of, and adherence to, user and functional requirements, and project master plans used to direct all validation activities. Developed and executed qualification protocols, test scripts and reports (installation, operation, performance, and vendor) that comprised the overall validation packages. Application was Oracle database backend.
- Managed diverse computer system validation and implementation project teams within the pharmaceutical industry, to successfully validate and implement chromatography and laboratory information management systems. Project teams included associates, client employees and contractors of varying abilities and geographic locations.
- Project manager in the development of a division-wide Master Computer Validation Plan and implementation strategy for major global pharmaceutical company to ensure that all systems and equipment were validated to the appropriate level. Validation levels were based on results of performing a risk analysis on regulatory exposure and business criticality. The plan included resource determination, prioritization, and identification of training and support requirements.
- Initiated, planned and executed a laboratory qualification program. This was the qualification and/or validation of all equipment, and all facilities (Water, Gas, Electric, Cabling, HVAC). This qualification was response to a FDA 483 observation and was accepted by the FDA.
- Evaluated, documented, implemented, and administered Chemical Information and Inventory Management Systems. Assessed client's needs and interacted with vendors to provide the data solutions as an integrated package. Application database was MS Access.

Operational & Organizational Management

- Provided career development to group of 18 associates of all technical levels, including mentoring, coaching, motivating, performance assessment, and professional development.

- Developed recruiting process guideline that was used by corporate recruiters and departmental associates involved in the process. This guideline provided the needed focus to recruit, interview and retain qualified associates. Once the process was instituted, department grew by 125% while maintaining a low turnover rate.
- Implemented and marketed a web cast seminar on "21 CFR Part 11: Lessons Learned" with 400 registrants and 200 attendees. Increased registration by 600% and attendance 800%, by follow up notifications and target marketing.
- Worked with account executives and corporate marketing in the development and support of strategic plans and proposals to expand departmental capabilities and extend our competitive edge. Presented departmental qualifications to clients via sales presentations. Assisted in the development of marketing collateral.

Laboratory Automation and Data Management

- Instituted an electronic data acquisition package to capture the large amounts of analytical data generated from automated spectrophotometers, balances, and robotic systems. Developed computerized applications to facilitate compliance with regulatory requirements by standardizing the statistical analysis and reporting of information and data. Applications increased productivity in data analysis, material management, training documentation, and documentation management.
- Programmed, validated, and maintained Automated Tablet Processing Workstation. System was developed for dose and content uniformity in the manufacturing QC environment. This system was interfaced to an HPLC and Waters ExpertEase chromatography data system. Developed all validation documentation for the systems.
- Developed four robotic applications using dual robotic arms to automate the quantitative analysis of pharmaceutical products. Developed Standard Operating Procedures to support the operation and validation of automated laboratory systems. Prepared and evaluated validation documents for the hardware and software of the robotic systems.

Instrumentation

- Developed calibration, maintenance and validation program for the analytical instrumentation used in the laboratories. Developed the SOPs to support program. Provided support for all analytical instruments in the program. Involved in troubleshooting and repairs for all analytical instruments in the Quality Control and Analytical R & D.
- Reviewed, recommended, installed, documented and validated numerous types of laboratory equipment and computer software for the ability to integrate to assay miniaturization or automated methods for high throughput screening.
- LABORATORY INSTRUMENTATION: (Representative, but not all inclusive)
  - Balances / pH Meters / Pipettors
  - Bar Code Equipment
  - Gel Electrophoresis
  - Gel Scanners / Densitometers
  - HPLC / GC / LC-MS
  - IR / FT-IR / NIR / UV /VIS Spectrophotometer
  - Liquid Handling Systems
  - (Tecan, Packard, Hamilton)
  - Microplate Reader (UV/VIS, Fluorescence, Luminescence, 96 / 384 Formats)
  - Refrigerator / Freezers
  - Robotic Systems (Thermo Scientific, Zymark, Beckman Coulter (Biomeck), SFA)
  - Total Organic Carbon Analyzer

PROFESSIONAL EXPERIENCE:

JAF CONSULTING, INC, Mullica Hill, New Jersey 1995-Present

Managing Consultant – Clients: Allergan, Animal Cell Therapies, Bristol Myers Squib (BMS), C2N Diagnostics, Cangene, Cephalon Inc., ChanTest, CPC Clinical Research, Cubist Pharmaceuticals Inc, DuPont-Pioneer, Eli Lilly (Chorus), EPL Archives, ePharma Solutions, Fort Dodge Animal Health, Georgetown University / DOD Blood Bank, Hoffman-La Roche, Hospira (formerly Mayne Pharma (USA)), ICON Clinical Research, Intercell, Innovative Formulations, Intrexon, Ironwood Pharmaceuticals, Johnson & Johnson (Centocor, Cilag, McNeil), Lovelace Respiratory Research Institute, Kellman Pharmaceutical Services, Lupin Pharmaceuticals, Inc., Medimmune, Merck & Co, Microcheck Inc., Mitsubishi Pharma America, Monsanto, OSI, Pfizer Inc. (Groton, NYC, MOPS), PRACS Institute, Protea Biosciences Group , Qualanex, Regeneron, Savient, Shire, Title 21 Software, TransTech Pharma, United States Pharmacopeia, University of Texas Medical Branch, VelQuest, Virginia Polytechnic Institute and State University (Virginia Tech), ViroPharma, Vizon SciTec Inc., Wallwork, Inc., Warner Chilcott Laboratories

CSC CORPORATION, FORMALLY FIRST CONSULTING GROUP, WAYNE, PENNSYLVANIA 1998-2001

Manager / Senior Consultant, Validation and Regulatory Practice – Clients: Schein Pharmaceuticals, GlaxoSmithKline, Solvay Pharmaceuticals, Johnson & Johnson

PFIZER, Morris Plains, New Jersey 1993-1995

Scientist, Manager Laboratory Automation Systems (Warner Lambert / Warner Chilcott)

GLAXOSMITHKLINE, King of Prussia, Pennsylvania 1987-1993

Biochemist 1, Biochemist 2, Co-op Student

EDUCATION:

- BS, Chemistry, St. Joseph's University, Philadelphia, Pennsylvania
- HITRUST Certified CSF Practitioner (CCSFP) (2018)
- Project Management: Preparation Courses for PMI PMP Certification (2019)
- Auditing: Preparation courses for Certified Information Systems Auditor CISA Certification (2019)
- Achieving Data Quality and integrity in Maximum Containment Laboratories, April 2014, Joint FDA and UTMB Conference
- Graduate Course Studies in Business Management and Information Technology: Rutgers University, Seton Hall University, Fairleigh Dickinson University
- Professional Development: Six Sigma Green Belt, Leadership, Coaching, Socratic Selling, Team Facilitation, Technical & Business Writing, and Presentation Performance Skills

AWARDS / HONORS:

- SQA Distinguished Speaker, 2017 - Present
- Pioneer in Laboratory Robotics, September 1992, Peer award for the development of new applications and designing unique solutions to technical problems.
- Zymark Medallion Award, August 1992, Successful completion and implementation of an Interfaced Automated Procedure, Zymark/Tecan interface.
- Zymark Medallion Award, May 1991, Successful completion and implementation of an Automated Procedure, S-2251 Chromogenic Assay.
- SmithKline Beecham Impact Award, August 1990, for significant contribution to the department in the area of laboratory robotics.

PROFESSIONAL AFFILIATIONS / MEMBERSHIPS:

- Society of Quality Assurance (SQA) - 2001-Present
- Society of Quality Assurance (SQA) – Education Committee (Elected) - 2015-Present
- Society of Quality Assurance (SQA) – Chair of the Education Committee - 2019
- SQA – Computer Validation Information Technology Compliance Specialty Section (CVIC) – 2001- Present
- SQA – Computer Validation Information Technology Compliance Specialty Section (Training Sub-Committee Chair – 2001- Present
- Society of Quality Assurance (SQA) – Quality Assurance Consulting Support SS (QACS)- 2017-Present
- Society of Quality Assurance (SQA) – Chair of the Quality Assurance Consulting Support Section 2018-Present
- Project Management Institute (PMI) 1999-Present
- American Chemical Society (ACS) 1987-Present
- Mid-Atlantic Laboratory Robotics Interest Group 1987-Present
- Parental Drug Association (PDA) 1999-Present
- International Society of Pharmaceutical Engineers (ISPE) – 2001 - Present
- Good Automated Manufacturing Practices (GAMP)– Laboratory Systems Special Interest Group

CONFERENCE PRESENTATIONS:

- Franchetti JA, Olin TR, Wheeler K, Bioanalytical Audit Due Diligence and Risk Management, Society of Quality Assurance Annual Meeting, April 2018
- Franchetti, What you need to know about GDPR!, Society of Quality Assurance Annual Meeting, April 2018
- Franchetti, Practical Application of OECD Technical Document 17, 254th ACS National Meeting and Exposition, Symposia on GLP for the Agrochemical Professional, August 2017
- Franchetti, GRC to meet regulators expectations, 254th ACS National Meeting and Exposition, Symposia on GLP for the Agrochemical Professional, August 2017
- Franchetti, Breaking down the FDA and MHRA Data Integrity Guidance, Society of Quality Assurance Special Symposium, September 2016
- Franchetti, Meister, Electronic and Digital Signatures, Society of Quality Assurance Annual Meeting, April 2016
- Franchetti, JA, Ferrell SR, Schuessler L, Auditing and Evaluating your Cloud, Society of Quality Assurance Cloud Symposium, October 2015
- Franchetti, JA, Advances in Cloud Technologies, Compliance Online Medical Device Summit, San Diego, September 2015
- Electronic Archiving Panel Discussion, SQA Annual Meeting, April 2015
- Franchetti, JA, Demystifying Change Management in the Validation Process, 67th Annual ASCLS-Central New England Convention, Providence, RI, April 2015
- Franchetti, JA, Compliant Use of Cloud Technology in the Life Science Industry, Provantis / CTC Laboratory Systems User Meeting, Tokyo, Japan, November 2013
- Franchetti, JA, Working within International Regulations in the Cloud, Applied Pharmaceutical Software Conference, Bensalem, PA, July 2011
- Franchetti JA, Electronic Equipment and Electronic Data, National Alliance of Independent Crop Consultants Annual Meeting, Fort Worth, TX, January 2011
- Moschetto F, Franchetti JA, Electronic Medical Records, Society of Quality Assurance Annual Meeting, April 2010, Cincinnati, Ohio.
- Franchetti JA, Auditing Electronic Data, Society of Quality Assurance Fall GLP Training, September 2007
- Franchetti JA, Electronic Data Capture in Clinical Trials, Society of Quality Assurance Fall GCP Training, September 2007
- Franchetti JA, Introduction to Computer Validation, Safety Pharmacology Society 1st Annual Meeting, Chicago, Il, November, 2001

WEBINAR PRESENTATIONS:

- Franchetti, JA, Navigating Global Regulations and Guidance around Data Integrity, Webinar, March 2018
- Franchetti, JA, Demystifying Change Management in the Validation Process, Webinar, January 2015
- Franchetti, JA, Compliant Use of Cloud Technology in the Life Science Industry, Webinar, December 2014
- Franchetti, JA, Mitigating Compliance Risks in Clinical Trials: Cloud Computing, FX Conferences Webinar, June 2011.

TRAINING PRESENTATIONS:

- Basic Good Manufacturing Practices, multiple Clients, April 2003-present
- SEND: Implementation, Validation and Outsourcing, Society of Quality Assurance, September 2018
- Data Integrity and Data Quality Workshop, Annually, Society of Quality Assurance, September 2016
- Basic Computer Validation Workshop, Twice per year, Society of Quality Assurance, April 2001-present
- Basic Good Clinical Practices, Twice per year, Society of Quality Assurance, April 2008-present
- Auditing Software and Data Providers with a Focus on Cloud, annually, Society of Quality Assurance, 2005 - present
- Electronic Archiving and Digital Decay, annually, Society of Quality Assurance, 2010 -Present
- Business Continuity and Disaster Recovery, annually, Society of Quality Assurance, 2011 – present

REGULATORY REQUIREMENTS & STANDARDS:

- 21 CFR 11 Electronic Records and Electronic Signatures
- 21 CFR 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- 21 CFR 210-211 Current Good Manufacturing Practices (GMP) for Finished Pharmaceuticals
- EudraLex: The Rules Governing Medicinal Products in the European Union Volume 4, Good Manufacturing Practice
- 21 CFR Part 58 Current Good Laboratory Practices (GLP)
- 21 CFR 820 FDA Quality System Regulations (QSR)
- FDA Good Clinical Practices (GCP)
- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- Sarbanes-Oxley Act 404
- ICH Good Clinical Practices (GCP)
- Good Distribution Practices (GDP)
- Good Automated Manuf. Practices (GAMP)
- ISO Standards (9000, 13485, 17025)
- Environmental Protection Agency (US EPA)
- European Union (EMA)
- OECD
- Japanese Ministry of Health
- COBIT 5
- AEMSA E-Liquid Manufacturing Standards v2.0
- HITECH Standards
- HIPAA Regulations

COMMUNITY ACTIVITIES:

- USA Ice Hockey Officiating Program, Regional Training Staff, 1989-Present
- USA Ice Hockey Official 1987 – Present
- NFHS Ice Hockey Official – 1999 – Present – 2008 NFHS Official of the Year
- NCAA Ice Hockey Official 1999 – Present
- USA Ice Hockey Coach 2000 – Present
- South Jersey Ice Hockey Officials Association, 2003-Present, Co-Founder, Past President (2003-2013), Vice President (2017-Present)
- CYO 8th Grade Girls Basketball Coach: 2014 - 2018
- Little League Baseball Manager 2000 - 2014

SOFTWARE APPLICATIONS EXPERIENCE: (Representative, but not all inclusive)

- Bar Code Systems
- Building Automation Systems
- Calibration Management Systems
- Chemical Inventory Management System
- Chromatography Data Management Systems (EMPOWER 2& 3, Expert Ease, Chemstation / OpenLab, HP RTE /LAS, Peak Pro, Turbochrom / AccessChrom)
- Clinical Data Management Systems
- Cognos Business Intelligence
- Configuration Management Systems
- Data Acquisition
- Data Warehouse Applications
- Database Applications (Oracle, SQL)
- Drug Stability Management
- Drug Safety and Pharmacovigilance (ARGUS, ARISg)
- Electronic Document Management Systems
- Electronic Lab Notebook Applications
- ERP Systems (SAP, JDE, OBI)
- Interactive Voice Response System (IVRS)
- Inventory Control (Sample / Chemical)
- Labeling (Sample)
- Laboratory Automation Systems
- Laboratory Information Management Systems
- MDL ISIS Host
- Microsoft Office Applications (Access / Excel / SharePoint, PowerPoint, Visio, Word)
- Microsoft Project / Project Central
- PLC / SCADA
- Robotics
- Sample / Inventory Management Applications
- Simulate8
- Statistical Systems (SAS, JMP)
- StudyLog
- Temperature Collection and Monitoring
- QMS
- Workflow / Process Management System

GAURAV KUMAR

PO BOX 925
MULLICA HILL, NJ 08062

PHONE: 856-241-1900
E-MAIL: INFO@JAFCONSULTING.COM

SUMMARY OF QUALIFICATIONS AND EXPERIENCE:

- Extensive and comprehensive experience as a Validation Engineer in Pharmaceutical and Biotech companies with emphasis on Computer System Validation (CSV), Equipment Validation and Manufacturing Systems Qualification.
- Experienced as a Validation Engineer / Technical Writer/ Validation Analyst/ Business Analyst working in FDA regulated environment per FDA 21 CFR part 11, 58, 210, 211, 820 and USP 1058 regulations and following GxP practices.
- Strong knowledge and background of Software Development Life Cycle (SDLC), Computer System Validation (CSV) and Validation Lifecycle (VLC) lifecycles and the Waterfall and Agile systems development models.
- Proficient in writing Validation Protocols, Installation Qualification (IQ) specification, Operation Qualification (OQ) Specification, Performance Qualification (PQ) Specification, Standard Operating Procedures (SOP), Work Instructions, Training Plans, Validation Master Plan (VMP), Validation Summary Report (VSR) Equipment Classification Forms per USP 1058, Vendor Protocol Assessment Form, and Design Qualification Forms.
- Experienced in writing Functional Requirement Specifications (FRS), User Requirements Specification (URS), System Design Specifications (SDS), Requirement Traceability Matrix, and Test Specification.
- Experienced in writing and executing test scripts for System Testing/ Validation Testing, Data Migration, Field Mapping and User Acceptance Testing (UAT).
- Experienced in handling/ closing testing and non-testing related issues for different levels of discrepancy/ defect/ deviation.
- Excellent working knowledge of owning change controls pertaining to system qualification/ re-qualification.
- Excellent problem-solving skills, team player, independent worker, quick learner and capability to perform well under pressure. Possess excellent documentation skills with good structured writing.

EXPERIENCE

JAF CONSULTING, INC. **MULLICA HILL, NJ**

Validation Consultant (Employee) *May 2019 to present*

Multiple Clients

- Prepared Validation Deliverables to support various projects in GMP and GLP environment (LIMS). Collaborated with key stakeholders (Management / Executives) and participants (Project Staff) to develop an overall objectives of validation projects and compliance strategies to consider the organizational business needs and regulatory expectations.
- Participated on Migration of Master control by assisting in the development of validation deliverables.
- Validation of electronic Informed Consent for EDC system by developing requirements and all test plans and scripts.
- Managing and performing all aspects of equipment qualifications and software validations including preparation of all required documents to ensure compliance of the system.
- Developing and execution of IQ, OQ and PQ protocols/test scripts.
- Ensuring 21CFRPart11 / 21CFRPart58 compliance is maintained throughout the system life cycle through change control procedures and periodic system reviews
- Ensuring GLP compliance throughout all operations by developing SOPs.

QUALITY SYSTEMS INTEGRATION **GREATER BOSTON AREA**

Validation Specialist (Contract) *March 2018 – May 2019*

- Providing Validation services for multiple client sites in New England area with prime focus on commissioning / qualification / Validation of: Analytical Instrument: ABB UV Detector
  Microscope, QC Water bath, FTIR, Enterprise Systems: QAD (ERP System), Master Control (LMS), Custom Excel Spreadsheet supporting Mfg Process, Verify Brand (Supply Chain System)
- Manufacturing Equipment/ Systems: Accu cutter system, Pouch sealer, Lyophilizer
- Utility Systems: Compressed Air system, Warehouse Mapping Temperature Distribution, Nitrogen, RO/DI system
- Quality Engineering: DI Audits, CSV Program Development for Client Sites

SANOFI **FRAMINGHAM, MA**

Validation Engineer (Contract) *June 2017 to Jan 2018*

- This project entailed Data Integrity remediation of QC Chemistry Equipment
- Performed GAP Analysis on equipment including but not limited to cIEF, Biacore Biosensors, Densitometer, DNA Threshold.
- Authored, Reviewed and Approved URS, System Specification, Functional Risk Assessment (FRA), IQ, OQ, PQ and Validation Summary reports for above listed equipment.
- Assisted Execution, Review, defect handling and closure associated with OQ testing.
- Implemented Change Controls for re-qualification of cIEF, Biacore Biosensors, Densitometer, DNA Threshold per Sanofi's policies and procedures.
- Supported CAPA, for all the Quality Control EMA observations.
- Validated Data Archival of QC Lab Systems using NuGenesis.
- Validated Empower per QC Chemistry Workflow.

AVECIA **MILFORD, MA**

Validation Engineer (Contract) *Feb 2017 to May 2017*

- This project entails commissioning and qualification of Manufacturing Systems:
- Authored, Reviewed and Executed Validation Plan, User Requirement Documents, Functional Requirement Document, Installation Qualification, Operational Qualification, Performance Qualification, Defect documents and Validation Summary Reports.
- Performed qualification on systems including but not limited to Site Supervisory System, Building Management System, Water Purification System, 70 cm purification column.
- Assisted Execution, Review, defect handling and closure associated with OQ testing.

JOHNSON & JOHNSON **RARITAN, NJ**

Validation Team Lead, Validation (Contract) *Apr 2016 to Jan 2017*

- This project entails validation of TrackWise Quality View reports for Complaints project. The testing utilized HP Application Lifecycle Management (HP ALM) testing tool using AGILE methodology.
- Authored, Reviewed and Approved Complaint Compliance Plan, Compliance Analysis
- Authored and Reviewed User Requirement Specifications, Functional Requirement Specifications for Complaints
- Managed designing the test scenarios for complaints process workflow.
- Managed designing the test scenarios for Quality View Report.
- Authored and Executed 36 Complaint Volume reports, 28 Complaint Parts Per Million, 8 Per-Complaint Reports, 8 CCV Metric Reports, 1 Electronic Medical Device Report.
- Managed Execution of 82 system test scripts for the Quality View test scripts
- Authored associated defects and got them resolved.

- Authored Reviewed and Approved UAT test scripts.
- Supervised End Business Users on execution and defect handling

SHIRE HUMAN GENETIC THERAPIES **LEXINGTON, MA**

Validation Engineer (Contract) *Jun 2015 to Mar 2016*

Manufacturing System Commissioning and Qualification

- This project entailed commissioning and qualification of several manufacturing equipment and systems
- Validate Manufacturing equipment and Systems including but not limited to Plant Information (PI) trending application, Building Automation System (BMS), Air Handling Units (AHU), Process Control System (PCS), Supervisory Control and Data Acquisition (SCADA), Ultra purification Chrome Skids per Manufacturing System Lifecycle (MSL) process following ISPE guidelines.
- Author, review and approved Validation Plan Protocols, Design Risk and Risk Assessment (DRRA) Project Requirements Documents (PRD), User Requirements Specifications, Traceability Matrix, Data Migration Plans, Installation, Operational and Performance Protocols, Validation Assessment for Change Controls, Investigations and Corrective and Preventative Actions (CAPA's).
- Coauthored Validation Maintenance for Controlled Applications
- Validate decommissioning of legacy equipment and systems.
- Reviewed and approved CAPA's for manufacturing system gaps.

Validation Engineer QC (Contract) - *Sep 2014 to Jun 2015*

Quality Control Analytical Instrument Qualification

- This project entailed the commissioning and qualification of several Quality controls system/ equipment per United States Pharmacopeia 1058 (USP-1058) along with performing PQ for enterprise systems as an end user.
- Validate the Quality Control equipment and systems per United States Pharmacopeia (USP section 1058), Food Drug Administration (FDA part 11, 210, 211 820) using Analytical Instrument Qualification (AIQ) and Good Automated Manufacturing Practice (GAMP) approach.
- Validate Quality Control equipment including but not limited to High-Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), Water Baths, Dionex, Ultra Performance Liquid Chromatography (UPLC), Total Organic Carbon (TOC) analyzer, Osmometer, Incubators/ Shakers, Cell analyzers, Fourier Transformation-Infrared (FT-IR), Fourier Transformation-Near Infrared (FT-NIR), Spectrophotometers, Microbial Identification System (MALDI-TOF), Mass Spectroscopy, Plate Readers and Potentiometric and Auto sampler titrators
- Validate applications pertaining to equipment including but not limited to Artel MVS Application Manager, LabX 2014, Labx 3.1, Janus Qualification and Syngene G Box: Chemi (Genesys and GeneTool)
- Author, review and execute Validation Plan Protocols, Equipment Classification forms as per USP 1058, Vendor Protocol Assessment Forms, Design Qualification, Conducting Gap Installation Operational and Performance Protocol, User Requirements, Requirement traceability matrix, decommissioning and System release forms Operational and Maintenance Standard Operating Procedure (SOP)
- Validate decommissioning of legacy equipment and systems.
- Excellent documentation skills in compliance with Good Documentation Practices (GDP). Experienced in performing Gap Analysis, reviewing and implementing Corrective and Preventive Actions (CAPA) and developing Remediation Plans to mitigate non-compliance.
- Performed Performance Qualification as a part of upgrade for Valgenesis 2.0, CMMS, STELA, DDMS and Trackwise Training Module.
- Proficient in using Valgenesis 2.0 to initiate compliance related documents including but not limited to Entity creation for a System that included following documents: Computerized Assessment Forms, IQ, OQ, PQ, RTM, System Test Report, Validation Project Plan and Validation Summary Report.
- Proficient in using CMMS for initiating Work Orders for equipment, requesting Asset ID's for systems.

- Validate QC raw materials, HPLC characterization and QC stability control sample results using Electronic Lab notebook (module in LIMS).
- Validated ELN LIMS reports for QC labs.

MCNEIL CONSUMER HEALTHCARE **FORT WASHINGTON, PA**

Validation Engineer (Contract) *Oct 2013 to Aug 2014*

EDM 2.0 –Enterprise Document Management System (Consent Decree project)

- This project encompassed the validation of the EDM version upgrade to 2.0, a Documentum platform (under consent decree) by the Food and Drug Administration. The main area of focus was on the system functionality required to implement the EDM 2.0 system and providing support to the QSE (Quality System Element) 2 team for the validation of EDM 2.0 application per McNeil Business requirements and also ensuring that the application is in alignment with FDA compliance guidelines using GAMP5 approach.
- Performed dry running activities to assess the functionality tested in Operational Qualification (OQ) test scripts provided by the vendor
- Executed OQ test scripts as part of the Development environment testing and maintained the Development phase error tracker to work in collaboration with the vendor in cases requiring configuration updates
- Developed test scripts for the staging environment testing and addressed compliance related comments during QA and Quantic review of the test scripts based on the risk associated to each functional requirement
- Responsible for coordinating script assignments to a team of 5 people for addressing QA and Quantic reviews
- Performed a Gap Analysis of the 21 CFR Part 11 requirements' traceability in the OQ test scripts for each document type in the EDM 2.0 system (Generic, Packaging, Manufacturing and Procedure documents).
- Performed a Gap Analysis of compound functional requirements to ensure the correct traceability in the scripts tested in the Staging environment
- Authored and developed Test Event Reports (TERs) for the testing of the implementation of the Staging environment and identified the required Corrective Actions to address the errors encountered
- Worked in collaboration with the technical team for any configuration updates as a result any odd system occurrence during Staging environment testing
- Actively involved in the User Acceptance Testing process in creating the data setup required for the testing by the business users
- Authored scripts testing McNeil security requirements and performance requirements for EDM 2.0
- Executed and Reviewed Migration script from EDM 1.0 to EDM 2.0
- Developed Executed and Reviewed IQ Production Verification Scripts and wrote TER associated with them.

Validation Engineer (Contract) - ETQ Symphony Validation (Consent Decree project) *Jan 2013 to Oct 2013*

- This project entailed the validation of the Investigation, Change Control and Corrective and Preventive Action (CAPA) modules of the ETQ (Excellence through Quality, Commercial off The Shelf web-based application) under Consent Decree commitment with Food and Drug Administration (FDA).
- Responsible for supporting the QSE (Quality System Element) 4 and 18 performing script writing and quality review activities.
- Validated the functionality and controls of the Change Control, Investigations and Corrective and Preventive Action Modules of the EtQ system
- Developed, authored and reviewed Operation Qualification Test Cases and Test Scripts for the EtQ System based on the Functional Requirement Specifications.
- Worked in conjunction with Quality Assurance reviewers to oversee any potential script issues
- Performed quality review activities on the Operation and Performance Qualification Test Scripts
- Involved in testing the application for 21 CFR Part 11 compliance related to Electronic Signatures and Electronic Records

- Maintained the Traceability Matrix to ensure the correct traceability of the Functional Requirements for Investigations, Change Control and CAPA modules
- Worked in collaboration with the Technical Team in case of functionality errors, user configuration and system errors
- Developed Test Defect Reports for any deviations occurring during System Execution of the Investigations, Change Control and CAPA module based on authored scripts
- Performed Peer Review activities on executed scripts before any Quality Review.

GENZYME **ALLSTON, MA**

Technical Writer (Contract) Manuf. System Remediation (Consent Decree project) - Jan 2012 to Dec 2012

- This project entailed the upgrade of Delta V system from RS3 ultra purification system along with technical writing of standard operating procedures
- Validated Manufacturing systems per FDA guidelines including but not limited to 21 CFR part 11, 210 and 211
- Authored Standard Operating Procedures for the downstream manufacturing equipment used in harvest of Fabrazyme.
- Validated upgrade of RS3 to Delta V ultra-purification system.
- Consent Decree specialist in performing GAP analysis and writing Remediation Plans.
- Working on FDA given deadlines for the manufacturing process up gradation.
- Authored and executed all validation documents including VMP, URS, FRS, IOQ, SOP, and VSR.
- Developed Test Scripts for GENIE Portal and Plateau Learning Module in both QA and production environment.
- Developed User Acceptance Testing and Criteria, Validation Strategy, Validation Master plan and process map of the Validation Strategy.
- Performed Manual and automated testing using HP Quality Center and HP QTP.
- Maintained Requirement Traceability Matrix for QA and other scriptwriters to track the current requirements.
- Performed compliance and quality investigations using Trackwise.
- Coordinated with QA groups and track and trend compliance / quality issues.

EDUCATION:

- **Master of Science in Biological Sciences,** New Jersey Institute of Technology
- **Bachelor of Science in Biotechnology,** Rajasthan University, India

COMPUTER PROFICIENCY:

- **Databases**: Oracle (8i, 10g, 11g)
- **Application Tools**: Documentum, Trackwise, Excellence through Quality (EtQ), Valgenesis 2.0, Computerized Maintenance Management System (CMMS), Drawing and Document Management System (DDMS), Stela Training Module, Crystal Reports, IBM COGNOS and Plateau Learning Module, Electronic Lab Notebook (ELN), Laboratory Information Management System (LIMS), Empower
- **Operating Systems**: Windows, UNIX, Fedora, Solaris, Macintosh, Linux.
- **Programing Languages**: Mathematica, Matlab, C, and C++

Appendix 2: Deviation Log

This log will be used to keep track of issued deviations. Make copies of this page as necessary.

Deviation Number	Test Script Number / Section	Brief Description of Amendment/Deviation	Status	Script Step Number(s)	Test Step	Site	Date Closed	Closed by	Impact	Criticality
eDocs-IQ-001	IQ	Hardware specifications listed in the expected results section of the IQ document didn't match actual specifications of the REDCap webserver. Installed Specifications were meeting and / or exceeding the specifications listed in the expected results.	Closed	1	1	Dev	05MAR20	Joe Franchetti	L	M
eDocs-I/PQ-002	N/A	IQ and PQ document were scheduled to be executed concurrently. No validation impact as this is a retrospective validation of the eDocs module.	Closed	N/A	N/A	Dev	05MAR20	Joe Franchetti	L	L
eDocs-I/PQ-003	PQ	Testing performed with one user role. Protocol generation errors on steps 32 and 33.	Closed	9	1, 12, 13, 24, 25, 29, 30, 35 and 38	Dev	23MAR20	Joe Franchetti	L	M
eDocs-I/PQ-004	PQ	Data backup and restore functionality was not tested in the PQ protocol as this test has been successfully completed and verified in the IQ test protocol.	Closed	10	11, 14, 15, 19, 22, 23, 28, 35, 44, and 45	Dev	23MAR20	Joe Franchetti	M	M
Reviewed By/ Date		Joseph A. Franchetti / Mar 31, 2020								

Page 1 of 1

Deviation and Attachment Log

Final Audit Report 2020-03-31

Created:	2020-03-31
By:	Gaurav Kumar (gauravkumar2309@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA2z_uatois-FXMItD7otpm3B92DbAnBYj

"Deviation and Attachment Log" History

Document created by Gaurav Kumar (gauravkumar2309@gmail.com)
2020-03-31 - 7:30:24 AM GMT- IP address: 103.106.28.250

Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature
2020-03-31 - 7:32:27 AM GMT

Email viewed by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-03-31 - 10:16:47 AM GMT- IP address: 73.196.185.110

Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)
Signature Date: 2020-03-31 - 10:17:36 AM GMT - Time Source: server- IP address: 73.196.185.110

Signed document emailed to Gaurav Kumar (gauravkumar2309@gmail.com) and Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-03-31 - 10:17:36 AM GMT

Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	eDocs-IQ-001	Script ID (s):	N/A	Script Step Number (s):	1
Test Cycle Number:	01	Execution Instance:	Development		

Complete description of the Deviation:

During Execution of IQ for eDocs step 1 required the tester to verify the following hardware and software specifications in the expected results:

VM Setup = 250Gb / 4Gb RAM
Hostname - HHVRIREDCP01
Run CentOS 6.5 Base Webserver
Install: Add MySQL
Install: PHP5
Install: MySQL PHP module

The actual results were the following:

VM Setup = 65 Gb / 23 Gb RAM
Hostname: oril10071p
Run RedHat Enterprise Linux 7
Install: Add MySQL
Install: PHP5
Install: MySQL PHP module

Expected results didn't match with Actual results on step 1. The root cause of this deviation is protocol generation error as the specifications listed in the expected results were used as placeholders that were never got updated until pre-execution approval of the IQ. There is no impact of this deviation on the execution of the IQ, as there is no infrastructure requirement listed in the URS document. VUMC IT is using the as needed software and hardware required to operate REDCap system.

Recorded By:	Gaurav Kumar	Date:	03MAR20

Corrective Action Plan:

No retest will be needed, as VUMC IT is using the as needed software and hardware required to operate REDCap system.

Test Re-execution required? NO **If YES, specify Test Script #, Step(s) including Login/Logout and Run #:**			
Impact (High, Med, Low)	Low	**Criticality (High, Med, Low)**	Low
Recorded By:	Gaurav Kumar	**Date:**	03MAR20
Approval to Proceed:	Joseph Franchetti	**Date:**	03Mar20
Corrective Action Verification:			
N/A			
Recorded By:	Gaurav Kumar	**Date:**	03MAR20
Technical Review:	Rob Taylor	**Date:**	04MAR20
Approval:		**Date:**	05MAR20

Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	eDocs-I/PQ-002	Script ID (s):	N/A	Script Step Number (s):	N/A
Test Cycle Number:	01	Execution Instance:	Development		
Complete description of the Deviation:					
The Performance Qualification (PQ) document will be executed concurrently with the Installation Qualification (IQ).					
Recorded By:	Gaurav Kumar		Date:	04MAR20	
Corrective Action Plan:					
Both of the documents will be executed concurrently, as there is no impact of configuration (IQ) on the operation / performance (PQ), as this is a retrospective validation verifying the eDocs core functionality along with 21 CFR part 11 and Data Integrity regulations.					
Test Re-execution required? **NO** If **YES**, specify Test Script #, Step(s) including Login/Logout and Run #:					
Impact (High, Med, Low)	Low		Criticality (High, Med, Low)	Low	
Recorded By:	Gaurav Kumar		Date:	04MAR20	
Approval to Proceed:	Joseph Franchetti		Date:	04Mar20	
Corrective Action Verification:					
N/A					
Recorded By:	Gaurav Kumar		Date:	04MAR20	
Technical Review:	Rob Taylor		Date:	04MAR20	
Approval:			Date:	05MAR20	

Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	eDocs – I/PQ - 003	Script ID (s):	N/A	Script Step Number (s):	1, 12, 13, 24, 25, 29, 30, 35 and 38
Test Cycle Number:	01	Execution Instance:	Development		

Complete description of the Deviation:

1. User Role 1 (Data Entry Analyst) user role will not be utilized for this testing from pre-requisite 1 as there is no user with Data entry analyst permission in the system.

2. Step 32 has a protocol generation error where the disabled permission(s) for Data Entry Analyst and Monitor / Auditor user role is incorrectly listed as disabled permission(s) for study coordinator. The intent of the step is to verify disabled permissions for Data Entry Analyst and Monitor / Auditor user roles.
3. Step 33 has a protocol generation error where the disabled permission(s) for Administrator user role is incorrectly listed as disabled permission(s) for study coordinator. The intent of the step is to verify only enabled permissions for Administrator user role. Administrator user role is outside of system operation function and will have all permissions enabled for system administration.

Recorded By:	Gaurav Kumar	Date:	10MAR2020

Corrective Action Plan:

1. There is no validation impact of this deviation on core system functionality as, direct user permissions test for user roles; Study Coordinator, Data Entry Analyst, Monitor / Auditor and Administrator is being tested on steps 31, 32 and 33.
2. All login logout steps for User Role 1 will be marked as N/A and will be carried out under User Role 2.
3. Step 32 will verify disabled user permissions for Data Entry Analyst and Monitor / Auditor user roles.
4. Step 33 will only verify enabled user permissions for Administrator user role.

Test Re-execution required? ☐ **YES** ☒ **NO**
If YES, specify Test Script #, Step(s) including Login/Logout and Run #:

Impact (High, Med, Low)	Low	Criticality (High, Med, Low)	Medium

Recorded By:	Gaurav Kumar	Date:	19MAR2020
Approval to Proceed:	Joseph Franchetti Joseph Franchetti	Date:	19MAR2020
Corrective Action Verification:			
1. Testing will be performed using User Role 2 from the pre-requisite section. Steps 1, 12, 13, 24, 25, 29, 30, 35 and 38 were marked as N/A with a reference to this Deviation. 2. Step 32 will verify disabled user permissions for Data Entry Analyst and Monitor / Auditor user roles along with a reference to this Deviation. 3. Step 33 will only verify enabled user permissions for Administrator, which would be all permissions. user role along with a reference to this Deviation.			
Recorded By:	Gaurav Kumar Gaurav Kumar	Date:	19MAR2020
Technical Review:	N/A	Date:	N/A
Approval:	Joseph Franchetti Joseph Franchetti	Date:	Mar 23, 2020

Signature: Gaurav Kumar
Gaurav Kumar (Mar 19, 2020)
Email: gkumar@jafconsulting.com

Signature: Joseph A. Franchetti
Email: jfranchetti@jafconsulting.com

eDocs – IPQ - 003

Final Audit Report 2020-03-23

Created:	2020-03-19
By:	Gaurav Kumar (gauravkumar2309@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4HzqcQ61qWzoRaylMtv-l7B9KEesxC8d

"eDocs – IPQ - 003" History

Document created by Gaurav Kumar (gauravkumar2309@gmail.com)
2020-03-19 - 5:33:42 PM GMT- IP address: 42.108.15.157

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2020-03-23 - 2:11:07 PM GMT

Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	eDocs – I/PQ – 004	Script ID (s):	N/A	Script Step Number (s):	11, 14, 15, 19, 22, 23, 28, 35, 44, and 45
Test Cycle Number:	01	Execution Instance:	Development		

Complete description of the Deviation:

Data backup and restore functionality will not be tested in the PQ protocol as this test has been successfully completed and verified in the IQ test protocol.

Recorded By:	Gaurav Kumar	Date:	Mar 19, 2020

Corrective Action Plan:

There is no corrective action for this deviation as the functionality tested on steps 11, 14, 15, 19, 22, 23, 28, 35, 44, and 45 has been completed and verified in eDocs Installation Qualification Test Protocol and Test Script step 7. Study ID 20 was created, and eDocs zip file was attached to the study id 20. The record was deleted from REDCap webserver and the attachment (eDocs zip file) was restored from the vault. A verification was done on the contents within the zip files from original and restored zip files. Test results from step will be leveraged to satisfy data backup and restore requirement.

Test Re-execution required? ☐ **YES** ☒ **NO**
If **YES**, specify Test Script #, Step(s) including Login/Logout and Run #:

Impact (High, Med, Low)	Medium	Criticality (High, Med, Low)	Medium
Recorded By:	Gaurav Kumar	Date:	Mar 19, 2020
Approval to Proceed:	Joseph Franchetti	Date:	Mar 23, 2020

Corrective Action Verification:			
Step 7 of eDocs Installation Qualification Test Protocol and Test Script has been successfully completed and verified. Steps 11, 14, 15, 19, 22, 23, 28, 35, 44 and 45 will be marked as N/A with a reference of this deviation.			
Recorded By:	Gaurav Kumar	Date:	Mar 19, 2020
Technical Review:	N/A	Date:	N/A
Approval:	Joseph Franchetti	Date:	Mar 23, 2020

Signature: Gaurav Kumar
Gaurav Kumar (Mar 19, 2020)
Email: gkumar@jafconsulting.com

Signature:
Email: jfranchetti@jafconsulting.com

eDocs – IPQ - 004

Final Audit Report 2020-03-23

Created:	2020-03-19
By:	Gaurav Kumar (gauravkumar2309@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAIcXa9LjhsA_ItKJzMYE76X_Bpn9DCIft

"eDocs – IPQ - 004" History

Document created by Gaurav Kumar (gauravkumar2309@gmail.com)
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2020-03-19 - 5:49:32 PM GMT- IP address: 42.108.30.181

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Signature Date: 2020-03-19 - 5:50:30 PM GMT - Time Source: server- IP address: 42.108.15.157

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Signature Date: 2020-03-23 - 2:10:26 PM GMT - Time Source: server- IP address: 107.152.104.239

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2020-03-23 - 2:10:26 PM GMT

Appendix 5: Attachment Reconciliation Log

Protocol Number / Run Number / Reference Section and Step	Attachment Number	Total Page Count
IQ / 01 / Section 6, step 1	001	2
IQ / 01 / Section 6, step 2	002	1
IQ / 01 / Section 6, step 5	003	2
IQ / 01 / Section 6, step 6	004	2
IQ / 01 / Section 6, step 7	005	3
IQ / 01 / Section 6, steps 8, 9, 10, 11 and 13	006	3
IQ / 01 / Section 6, step 12	007	1
IQ / 01 / Section 6, step 14	008	1
PQ / 01 / PQ eDocs, Step 1	001	1

Protocol Number / Run Number / Reference Section and Step	Attachment Number	Total Page Count
PQ / 01 / PQ eDocs, Step 2	002	1
PQ / 01 / PQ eDocs, Step 3	003	1
PQ / 01 / PQ eDocs, Step 4	004	1
PQ / 01 / PQ eDocs, Step 26	005	1
PQ / 01 / PQ eDocs, Step 36	006	1
PQ / 01 / PQ eDocs, Step 40	007	1
PQ / 01 / PQ eDocs, Step 49	008	1
PQ / 01 / PQ eDocs, Step 51	009	3
Reviewed By / Date	/ Mar 31, 2020	

Page 2 of 2

Deviation and Attachment Log

Final Audit Report 2020-03-31

Created:	2020-03-31
By:	Gaurav Kumar (gauravkumar2309@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA2z_uatois-FXMItD7otpm3B92DbAnBYj

"Deviation and Attachment Log" History

Document created by Gaurav Kumar (gauravkumar2309@gmail.com)
2020-03-31 - 7:30:24 AM GMT- IP address: 103.106.28.250

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2020-03-31 - 7:32:27 AM GMT

Email viewed by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-03-31 - 10:16:47 AM GMT- IP address: 73.196.185.110

Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)
Signature Date: 2020-03-31 - 10:17:36 AM GMT - Time Source: server- IP address: 73.196.185.110

Signed document emailed to Gaurav Kumar (gauravkumar2309@gmail.com) and Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-03-31 - 10:17:36 AM GMT

REDCap eDocs Validation Summary Report Final v1

Final Audit Report 2020-03-31

Created:	2020-03-31
By:	Joseph Franchetti (jfranchetti@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAPzIrp8135tjI9W6FF_FYY7-LEYPlp7Pk

"REDCap eDocs Validation Summary Report Final v1" History

Document created by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-03-31 - 4:03:44 PM GMT- IP address: 73.196.185.110

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2020-03-31 - 4:04:50 PM GMT

Document emailed to Colleen E. Lawrence (colleen.lawrence@vumc.org) for signature
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Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature
2020-03-31 - 4:04:51 PM GMT

Document emailed to Paul A. Harris (paul.a.harris@vumc.org) for signature
2020-03-31 - 4:04:51 PM GMT

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Signature Date: 2020-03-31 - 4:05:02 PM GMT - Time Source: server- IP address: 73.196.185.110

Email viewed by Rob Taylor (rob.taylor@vumc.org)
2020-03-31 - 4:05:15 PM GMT- IP address: 160.129.251.128

Email viewed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
2020-03-31 - 4:07:53 PM GMT- IP address: 160.129.251.127

Email viewed by Paul A. Harris (paul.a.harris@vumc.org)
2020-03-31 - 4:08:03 PM GMT- IP address: 68.53.113.176

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Signature Date: 2020-03-31 - 4:09:40 PM GMT - Time Source: server- IP address: 160.129.251.127

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Signature Date: 2020-03-31 - 4:35:37 PM GMT - Time Source: server- IP address: 103.106.28.250

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2020-03-31 - 4:35:37 PM GMT