Backlog QC API – Metropolitan Area Frankfurt 2014

Position: QC Consultant

Duration: 9 months

- Checking and Processing of OOS events in retrospect (release and stability)
- Checking and Processing of deviations in retrospect (release and stability)
- Checking and Processing of CAPA in retrospect (release and stability)
- Organization and processing of meetings with labs and experts
- Determination of further measures and closing of open measures from deviations
- Processing of analytical procedures in co-operation with experts
- Adaptation of methods due to open measures from CAPAs
- Editing of documents
- Review and editing of SOP
- Investigation in data bases regarding test procedures, specifications
- FDA Remediation Support
- Data administration and actualization in line of projects
- Guidance of Projects and Boards
- Project Management and Organization of Steering Boards

QA – Metropolitan Area Berlin 2015

Position: QA Consultant

Duration: 30 days

- Check of qualification documents (DQ, IQ, OQ & PQ) and reports for the introducing eDMS system
- Assistance for the implementation of the qualification
- Support for the implementation of the eDMS system (e. g. process for the implementation of existing documents)
- Ghostwriter for SOP's: Deviation Management, Contract Management, Excel Spreadsheet Validation, Quality Risk Management (QRM)
- Revision QA-Manual
- Preparation and creation of a template for APR/PQR

QA Medical devices – Metropolitan Area Frankfurt 2015

Position: QA Consultant Medical devices

Duration: 2 months

- Development of the needed documents to put new manufacturing processes into practice
- Plan, coordination and documentation of all activities regarding the qualification (OQ, PQ) and validation activities (Process – and cleaning validation)
- Working in clean room Class C

- Taking ownership in root cause investigations and initiating corrective and preventative activities (CAPA)
- Communication of development results in scientific reports
- Implementation of the latest industry standards together with the regulatory expectations and making sure that the done work accordingly
- Report to the Head of Manufacturing - and occasionally carry out tasks for the Technical Lead
- Internal the work in cooperation with the production department, the Quality Assurance, Regulatory and Quality Control departments

QA Diagnostics – Metropolitan Area Zürich 2015/2016

Position: QA Consultant

Duration: 12 months

- Monitoring and consulting of compliance of regulatory guidelines and definition of requirements of the quality management system for specifications in the area of manufacturing and testing of different product line,
- Proceeding of Q-reviews for deviations; proofing on regulatory integrity/ accuracy, release of these events,
- Proceeding of Q-reviews for changes on regulatory integrity/ accuracy,
- Collaboration for the preparation of statistics for the product monitoring like failure statistics and quarterly report
- Review and release of documents
- FDA Readiness Support
- Support within several departments
- Investigation and optimization of processes
- Deviation Management
- Change Management
- Review and release of batch records from the Device Production

QA/QC – Thuringia 2016

Position: Head of Quality

Duration: 2,5 months

- Interimposition as Head of Quality responsible for 17 employees
- Technical and disciplinary responsibility for all employees
- Responsibility for the quality and for tests in line of manufacturing of primary packaging materials for the pharmaceutical industry
- FDA Readiness Support
- Release of quality-related documents
- Energy management / environmental management
- Responsible for budget

QC – Düsseldorf 2016

Position: Interim Head of QC Biochemistry team

Duration: 8 Months

- FDA Readiness and Remediation Support
- Provide guidance and leadership to the QC Biochemistry team
- Provide an environment that fosters learning, open communication, collaboration, and teamwork
- Establish development plans and train staff to ensure technical proficiency is current to meet the needs of the department
- Supervise quality control laboratory activities including drug substance and drug product release testing, in process testing and stability studies
- Ensure GMP compliance of the QC Biochemistry Laboratory including sample management, raw data management, instrument and equipment management
- Prepare and/or review protocols and reports related to QC Biochemistry
- Lead investigations on Deviations and OOS results. Prepare and technically review Deviation, CAPA and Change Control documents for the QC Biochemistry group
- Provide technical guidance in resolving issues as well as making process/method improvements
- Oversee the development of and approve SOPs, test methods, protocols, reports, and other quality documentation of the Laboratory
- Provide quality and/or analytical expertise to other groups of Dynavax including MS&T or Manufacturing

QC – Berlin 2017

Position: Head of Quality Control

Duration: 1 Month

- May execute QC checks of Medicinal Products and other quality critical Clinical Trial Materials during receipt, production and distribution
- Oversee all Quality Control activities in local depot/warehouse
- Instruct and train QC staff and other depot staff as needed
- Perform QC release of Medicinal Product batches and batches of other quality critical Clinical Trial Materials (CTM)
- Oversee premise and equipment (P&E) maintenance and cleaning
- Approve Product Specifications and Master Batch Records
- Review and approve Production Batch Records and Test Records
- Perform and support P&E qualification/validation activities as appropriate
- Oversee local depot and production (D&P) related change control procedures and quality issue (QI) reporting

QA/QC – Saxonia 2017

Position: QA Consultant

Duration: 3 Months

- Preparation and Proceeding of Self Inspections
- Handling with regulatory questions
- Creation of PQR
- Organisation of a new training concept for new QC technicians with following topics: Lab safety, GMP in the QC lab, Organisation and workflow in the QC lab
- Metal impurities ICH Q3D
- Data integrity in QC
- FDA Remediation Support
- Quality Assurance Agreements
- Handling and creation of SOP
- Excel Sheet Validation
- Quality Assurance Agreement
- Investigation to dietary supplements
- Methode Expertise

QA/QC – Metropolitan Area Frankfurt 2017/2018

Position: QC Consultant

Duration: 11 Months

- Handlich of CAPAs
- Training of regulatory questions
- Handling of SOPs
- Special questions of HPLC applications
- Creation and training of equipment manuals
- Preparation of audits

QA/QC – Thuringia 2018

Position: QC Consultant

Duration: 3 Months

- Qualification of analytical equipment
    - Review of revised HLRA (high level risk assessment) for analytical equipment
    - Requalification of analytical inventory equipment according to give templates with the focus data integrity

    - Initial qualification of an analytical device (IQ/ OQ/ PQ)
    - Review of the efficiency of the established qualification process in QC
- Processing of changes in the quality assurance
    - Assessment of changes from the point of quality assurance
    - Review of measures for the establishment of changes
    - Überprüfung Implementierung
    - Review implementation
    - Independent review of the efficacy of changes

QA – Metropolitian Area Düsseldorf 2018

Position: QA Consultant

Duration: expected 3 Months

- Creation of PQR/APR
- Bracketing of supplier and products for improvement of PQR creation management

QC – Metropolitian Area Mannheim 2018

Position: QC Consultant

Duration: 3 Months

- Creation, editing and completion of master specifications and testing specifications in line of a preparation according to a upcoming FDA inspection

QA/QC – Metropolitan Area Frankfurt 2018/2019

Position: QC Consultant

Duration: estimated 15 Months

- Method validation
- Creation of validation reports
- Creation of validation plans
- Adaption of methods

QA/QC – Thuringia 2019/2020

Position: QC Consultant

Duration: 3 Months

- Product validation reports
- Media Fill reports

QC – Lower Saxony 2019

Position: Head of QC

Duration: 8 months

- Approvals excipients
- Laboratory organization
- Method transfer
- Project supervision
- Qualification of equipment
- Audits
- Hygiene and environmental monitoring
- Projects for the establishment of trending methods

QA/QC – Thuringia 2019/2020

Position : QA Consultant

Duration: 2 Months

- Media Fill Reports
- Batch Record Review

QA/QC – Thuringia 2020

Duration: 1 Month

Position: QA/QC Consultant

- Adaptation and grouping of method validations

QA/QC – 2020 - Frankfurt area

Position: QA/QC Consultant

Duration: 9 Months

- GAP assessments when comparing legal regulations and international rules with the local SOP landscape.
- Closing GAPs by adapting local regulations in consultation with local management
- Facilitation of meetings
- Writing SOPs

QA/QC – 2020/2021 - Tübingen

Position: QA/QC Consultant

Dauer: 12 Months

- GAP assessments when comparing legal regulations and international rules with the local SOP landscape.
- Closing GAPs by adapting local regulations in consultation with local management
- Facilitation of meetings
- Writing SOPs

QA/QC – 2021 - Frankfurt area

Position: QA/QC Consultant

Duration: 3 Months

- GAP assessments when comparing legal regulations and international rules with the local SOP landscape.
- Closing GAPs by adapting local regulations in consultation with local management
- Facilitation of meetings
- Writing SOPs

QC – 2021 - Heidelberg

Position: Head of QC

Duration: 13 Months

- Provided technical leadership to over 90 employees on all QC related operations
- Responsible for the launch of analytical projects for the manufacture of two vaccines and other projects with customers
- Release of CoA
- Release and technical responsibility for transfer documents, validation and qualification documents
- Implementation of a LIMS system for releases and stabilities
- Organization of meetings and collaboration with various customers
- Market release with regard to CoC
- Preparation of pandemic preparedness of the Federal Republic of Germany with regard to the availability of vaccines

QC 2022 Greater Gießen

Position : QC Consultant

Duration : 2 Months

- Preparation and follow-up of the authority audit by the regional council
- Preparation and follow-up of measures resulting from the authority audit or that have to be prepared
- Evaluation of OOS events from the years 2019 -2022 with regard to compliance with the authority regulations

QC – Thüringen 2022/2023

Duration: 8 Months

Position: QC Consultant

- Support of the microbiology department
- Review of environmental monitoring, batch monitoring
- Personnel monitoring
- Creation of deviations and events
- Creation of trend reports for batch and environment monitoring

QC – Hessen 2023/2024

Duration: 12 months

Position: QC Consultant

- Consulting on QC laboratories on set-up/sampling/evaluation of stability studies and data regarding planning, implementation and evaluation of stability studies and data
- Consulting on selection of appropriate stability conditions, sampling strategy, and determination of appropriate analytical methods
- Ensure that stability studies comply with applicable regulations and standards and that data collected are reliable and meaningful
- Consulting on the organization and execution of stability study events, such as stability reviews and audits
- Ensure that all relevant documents and data are available, and that the execution of events complies with applicable regulations and standards
- Trending of stability data to identify potential deviations and trends early and take appropriate action
- Analyze stability data and identify potential trends and deviations, establish appropriate criteria for trend analysis, and monitor effectiveness of corrective actions
- Consulting on selection and qualification of service providers for outsourcing activities related to stability studies, such as warehousing and analytics. Establish

appropriate criteria for selection and qualification of service providers and monitor compliance with agreed standards and regulations
- Ensure that service providers implement appropriate quality assurance measures and that the results of the services meet the expected requirements

QC/QA – Berlin 2023

Duration: 6 months

Position: QC/QA Consultant

- Processing Backlog Product Quality Report (PQR)
- Compilation of data from SAP and other data sources
- Review of valid SOPs and forms regarding PQR
- Creation of PQRs based on priority lists