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 – 2021/2022 - Heidelberg

Position: Head of QC

Duration: 9 Months

- Provided technical leadership to over 80 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

QC – 2022 - Hessen

Position: Consultant QC

Dauer: 1,5 Months

- Preparation of the inspection of the Regional Council of Hessen for the QC
- Retrospective view and evaluation of OOX operations 2019-2021.
- SOP editing

QC – 2022 - Heidelberg

Position: Head of Protein Analytics, Deputy LQC

Dauer: 3 Months

- Technical leadership of more than 15 employees on all QC-typical procedures of protein analytics
- Support for the new Head of Quality Control