Henriette Hansen
B.Sc. Engineer Chemistry

Senior specialist Pharma production

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Competences

- Project Management
- Establishment of strategy concerning calibration of instrumentation including for calibration points and frequency
- Handling of GMP and quality assurance in general including change control and deviations
- Construction of quality system including generation of instructions and templates
- Handling of strategy plan concerning commissioning/qualification/validation including planning of daily activities
- Writing, review and approval of validation master plans, protocols, and reports

Key results

GMP and quality assurance Theoretical knowledge and practical experience as well. I have a fine understanding of quality management and the importance of audit readiness including structuring of quality systems, change management and handling of corrective and preventive actions and deviations.
Commissioning/Qualification/Validation of equipment, process plants, utilities, and facilities. Generally, planning, execution and documentation of factory and site acceptance tests, design, installation, and operational qualification as well as process validation and thermal validation including documents such as validation master plans, requirement specifications, risk assessments, protocols and reports.
Calibration forms a significant part of my experience including ISO- accreditation and activities.
Project management in relation to management of technical projects covering the responsibility for quality, time, and costs related to rebuilding and purchase of new production equipment.

Software/Standards

- FDA 21 CFR Part 1 Electronic Records; Electrc. Signatures
- FDA 21 CFR Part 210 CGMP in Manufacturing, Processing, Packing, or Holding of Drugs
- FDA 21 CFR Part 211 CGMP for Finished Pharmaceuticals
- FDA 21 CFR Part 820 Quality System Regulation
- EudraLex Volume 4 Good Manufacturing Practice
- EudraLex Volume 4 Annex 1 Sterile Medicinal Products
- EudraLex Volume 4 Annes 11 Computerised Systems
- EudraLex Volume 4 Annex 15 Qualification and validation
- ICH Q7 GMP Guide for Active Pharmaceutical Ingredients
- ICH Q9 Quality Risk Management
- ICH Q10 Pharmaceutical Quality System
- ASTM 2500E Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
- ISO 13485 Quality Management Systems
- ISO 17025 Testing and Calibration Laboratories
- ISO 17665 Sterilization of Health Care Products, Moist heat

Personal Characteristics

Structured, purposeful, and persistent with a high focus on bringing an idea to the practical level, getting things done and reach goals on time.

Pragmatic, solution-orientated and adapt the situation/opportunities.

Take care of the quality, pay attention to details, and go in depth when needed.

Good at balancing the efforts between actions "here and now" and initiatives with a more long-term perspective.

Positive, sympathetic, and thinks before acting.

Open minded and respectful concerning the knowledge of others and personal contributions.

References

Medicologic A/S (present)
Senior Consultant

Cook Medical
Test & Validation Manager

Element Metech
Development Manager Validation Site Manager Life Science
Team Leader Validation and validation engineer

Novo Nordisk
Validation responsible (BPK Packaging Ka)

Orkla Care
Engineering Manager
Project Engineer, Qualification Chemist

Novo Nordisk
Project Manager

LEO Pharma
Validation Engineer

AJ Vaccines
Team Leader Calibration GMP-Engineer

Rigshospitalets Apotek
Validation Engineer (Sterile Production)