Chemical Analysis

Focus Areas

- Automation of analytical techniques
- Spectroscopic techniques
- Process analytical technology, Real time release testing
- Life-cycle approach of analytical technologies
- Digital applications in analytical technology
- Data integrity and data governance
- GC reference standard development
- Impurities characterization, including inorganic, organic and mutagenic (extractables and leachables)
- Risk-based approaches.

Key Issues/Goals

1. **Development of GC standards for Industry 4.0:** PAT
2. Chemometrics
3. Environmentally friendly analytical techniques.
4. Impurities

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Chromatography
- Spectroscopy
- Pharmaceutical and analytical waters
- Analytical techniques used in pharmaceutical quality control.
    - Pharmaceutical quality control and compliance
    - Preparation and control of water for pharmaceutical products
    - Data quality and data management
- Toxicological assessment
- Relevant expertise in focus areas above
- Solid-state NMR
- qNMR
- Environmentally friendly analytical techniques expertise
- International harmonization experience
- Good management practices acumen

Dosage Forms

Focus Areas

- Quality and performance tests for all types of dosage forms
- Complex products such as complex injectables, ophthalmics, topicals & transdermal, nasal & inhalation products

Key Issues/Goals

- Quality and performance tests for all types of dosage forms and complex products

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Quality control and manufacturing knowledge of all types of dosage forms and complex products:
    - Oral
    - Transdermal
    - Parenterals
    - Mucosal
    - Combination Products
    - Nasal and Inhalation
    - In-process control of all types of dosage forms

Materials Physical Properties Characterization

Focus Areas

- Standards and guidelines for analytical procedures for the material's physical properties characterization and quality control, including the input and in-process materials (e.g., particles, powders, liquids, slurries) used in the manufacturing of a drug product and/or its components (excipients, drug substance, etc.).

Key Issues/Goals

- Pharmaceutical Continuous Manufacturing
- Material physical properties characterization (Wetting, electrostatic, Compaction Simulation, Rheological properties, etc.)
- Particle Size and Shape Measurement Techniques (e.g., Scattering Techniques, Microscopy, Image Analysis, Analytical Sieving and X-ray Diffraction Techniques)
- Real-Time Release Testing
- Process Analytical Technology
- Analytical technics to support Complex Generics topics
- Nanomaterial Analytical characterization

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Analytical Techniques of Physical Properties used in Pharmaceutical Quality Control
- Crystals Characterization (e.g. Microscopy, X-Ray Powder Diffraction, etc.)
- Image Analysis of Pharmaceutical Systems
- Optical Image Analysis
- Measurement of Rheological Parameters
- Permeability
- Phase Transitions
- Thermal Analysis (DSC, TGA, Hot-Stage Microscopy, Eutectic Impurity Analysis)
- Inorganic Impurities
- Nanotechnology
- Osmolality and Osmolarity
- Solubility Measurement
- Resuspendability

Microbiology

Focus Areas

- Rapid/Modern Microbiological Methods
- Monocyte Activation Test, replacement tests for the Rabbit Pyrogen Test
- In-process bioburden
- Microbiological contamination control strategy
- Sterility Assurance
- Sterilization

Key Issues/Goals

- Continuing the work to modernize endotoxins and pyrogens tests, moving away from animals and reagents derived from animals
- Continue the work for in-process bioburden, creating useful standards
- Build the confidence to publish new methods through retrieving data and developing method
- High demanding of rapid microbiological methods

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Monocyte Activation Test (MAT), Pyrogen Tests
- Bacterial Endotoxins Test – Recombinant reagents
- Rapid/Modern Microbiological methods

- Microbiological contamination control strategy and sterility assurance.
- Bioburden and Environmental Control
- Microbiological method validation and comparability
- Dietary supplements and food ingredients
- Cell and gene therapy
- Molecular Biology
- Compounding Preparation

Packaging and Distribution

Focus Areas

- Packaging sustainability, Recycled plastic materials, Biodegradable and sustainable packaging materials
- Good Distribution Practices (GDP), Temperature control management, Temperature excursion management, Temperature mapping, Distribution packaging system
- Packaging suitability, Biocompatibility, Polymer chemistry, Glass quality, Extractable and Leachables

Key Issues/Goals

- Material Chemistry and Properties:
    - Chemical composition and physical properties of packaging materials.
    - Material behavior under different conditions (e.g., temperature, humidity, stress).
- Polymer Science:
    - Polymers used for packaging (e.g., plastics, elastomers).
    - Polymer processing, degradation, and stability.
- Glass Quality and Properties:
    - Glass as a packaging material.
    - Glass quality, durability, and compatibility with products.
- Biocompatibility:
    - Packaging suitability and compatibility
    - Packaging materials for safety in contact with products.
- Sustainability and Eco-Friendly Materials:
    - Sustainable packaging solutions.
    - Bio-based plastics, recycled materials, and biodegradability.
- Packaging Suitability:
    - Assessing material suitability for specific products
    - Factors for protection and preservation
- Extractables and Leachables:
    - Identify and quantify substances that can migrate from packaging materials.
- Packaging Testing Methods:
    - Testing techniques (e.g., tensile strength, barrier properties, permeability).
    - Material performance.

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- **Material science:** Knowledge of materials used in pharmaceutical packaging, including polymers, glass, metals, and elastomers, and their properties such as barrier properties, compatibility, and stability.
- **Packaging design:** Expertise in designing packaging systems that ensure product stability, integrity, and safety throughout the product lifecycle, considering factors such as shelf-life, transportation, and end-user usability.
- **Material/solution interactions:** Understanding of the principles governing interactions between materials (such as packaging, containers, and manufacturing equipment) and pharmaceutical solutions, including knowledge of migration modeling and drug binding.
- **Material characterization:** Knowledge of materials used in pharmaceutical packaging, manufacturing, and drug delivery systems, including polymers, elastomers, glass, metals, and their potential interactions with drug products.
- **Analytical chemistry:** Proficiency in various analytical techniques, including chromatography (LC, GC, IC), mass spectrometry (MS), spectroscopy (UV, IR, NMR), and wet chemical methods. This expertise is crucial for identifying and quantifying extractable and leachable compounds.
- **Instrumentation:** Proficiency in operating and maintaining advanced analytical instruments used in the detection and analysis of extractables and leachables, including specialized chromatography and spectroscopy equipment.
- **Supply chain management:** Knowledge of supply chain principles, including inventory management, logistics, warehousing, and transportation.
- **Temperature control and monitoring:** Expertise in maintaining the integrity of temperature-sensitive products through proper storage, handling, and monitoring techniques.
- **Sustainability and environmental considerations:** Understanding of sustainable packaging practices, including recyclability, biodegradability, and eco-friendly materials, to minimize environmental impact and meet corporate sustainability goals.
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Pharmaceutical Analysis Lifecycle – Data Science

Focus Areas

- Analytical Procedures Lifecycle
- Chemometrics
- Ongoing procedure performance verification, statistical tools for process/procedure performance monitoring (multivariate and univariate procedures)
- Measurement Uncertainty and Total Analytical Error – role throughout procedure lifecycle
- Analytical Instrument Qualification

Key Issues/Goals

- Analytical Procedure Validation: APLC JS/OPPV JS/Chemometrics JS
- Statistical tools for process/procedure performance monitoring, example control charting (multivariate and univariate procedures)
- Measurement Uncertainty and Total Analytical Error – role throughout procedure lifecycle
- Replication Strategy
- Chemometrics
- Design of Experiments
- Analytical Instrument Qualification (metrology)
- Volumetric Apparatus
- Balances
- Analytical procedures quality risk management

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Analytical procedure validation, Verification and Transfer
- Analytical procedure lifecycle
- Chemometrics
- Statistical tools for process/procedure performance monitoring, measurement uncertainty and total analytical error
- ISO guides – MU, TMU, Control Charts.
- Design of Experiments
- Development and validation of analytical procedures for biologics
- Analytical Instrument Qualification lifecycle
- Volumetric Apparatus
- Balances
- Expertise in Metrology
- Multivariate and univariate procedures
- Analytical procedures Quality risk management

Statistics

Focus Areas

- Uniformity of Dosage units; Content Uniformity for Large Samples
- Statistical Quality control
- Sampling procedures
- Analytical Procedure Equivalency
- Bioassay

- Multivariate data analysis

Key Issues/Goals

- Bioassay
- Analytical procedure comparability
- Sampling techniques and procedures

Required Qualifications (Technical Skills)

The candidate should have experience in one or more of the following areas:

- Applications of statistical methods in Pharma industry
- Probability
- Statistical Inference
- Sampling techniques
- Statistical Quality Control
- Understanding Process Variability
- Bioassay (Development, validation, and lab analysis experience)
- Analytical method validation including microbiological method.
- Non-linear models
- An understanding of Quality by Design and Experimental Designs.
- Data science and Machine learning concepts.
- Familiarity with regulatory and pharmacopeial standards.
- Chemometrics