cencora
PharmaLex

Unlocking data-and-analytics excellence in CMC

Unlocking data-and-analytics excellence in chemistry, manufacturing, and controls

Chemistry, manufacturing, and controls (CMC) describe critical activities during development and regulatory approval of pharmaceutical and biopharmaceutical products. PharmaLex's data strategy and statistics dedicated team specializes in leveraging an integrated data-and-analytics approach to accelerate quality throughout the drug development and production lifecycle.

Integration of data strategy and statistics

Our expert team integrates innovative data strategy and statistical methodologies with a profound understanding of modern drug development and production platforms.

Designed for essential connections

PharmaLex's data strategy and statistics methodologies, grounded in thoroughly designed experiments and effective uncertainty management, yield robust quality predictions. Our commitment to Quality by Design (QbD) empowers processes and analytical laboratories, fosters scientific understanding and reduces development time. This happens using the advanced Frequentist and Bayesian models.

Shortening development timelines

In the face of increasing complexity in molecules, therapeutic approaches, digitalization, bioprocessing, scale-up, and regulatory demands, we stand as your dedicated partner. From research and development to validation, manufacturing, digitalization, and regulatory compliance, we help to shorten timelines of medical product development.

Choose PharmaLex for expertise and unwavering dedication to excellence in CMC data-and-analytics

Data and IT architecture

- Understand your business processes and drive forward the digitalization of your lab operations.
- Benefit from thorough planning and implementation of data and IT architecture.
- Integrate and standardize distributed CMC data in a governed environment to facilitate compliance with ICH-Q11.

Processes

- Implement QbD from early development and characterization to Process Performance Qualification (PPQ).
- Provide a comprehensive view and simulation of multi-step processes and multi-Critical Quality Attributes (CQAs).
- Offer strategic guidance for process development.
- Design and analyze PPQ studies.
- Implement Continued Process Verification in a digitalized environment.
- Develop digital twins for enhanced process understanding.
- Ensure comparability during tech transfer.

Formulation

- Utilize QbD for formulation optimization and stability enhancement.
- Employ advanced stability modeling for biological products.
- Predict long-term stability, shelf-life, and internal release limits.
- Develop software to automate the production of stability reports.

Assays

- Implement Analytical Procedure Lifecycle and Analytical Quality by Design (AQbD) principles.
- Validate Total Analytical Error and support compliance with guidelines (ICH Q2/Q14/M10, USP 1220, USP 1020, USP 1032, 1033, 1034).
- Define ATP from process data.
- Develop software to automate validation reports production.

Automation

- Automate repetitive analysis and reporting tasks.
- Establish data pipelines to connect various data sources.
- Develop qualified applications and software solutions.

Regulatory

- Address inquiries related to Investigational New Drug (IND)/Biologics License Application (BLA) submissions.
- Ensure compliance with regulatory guidance and enhance processes accordingly.
- Narrative for regulatory documents and interactions provides clarity and coherence while ensuring a concise and strategic presentation.

Contact us
www.pharmalex.com/contact-us