

The logo for VTU, consisting of the letters 'VTU' in a bold, white, sans-serif font with a horizontal line underneath. The background of the entire page is a complex network of glowing blue lines and various white icons representing science, technology, and industry, such as a heart with a pulse line, a clipboard with a graph, a molecular structure, and a shield.

VTU

ANALYTICAL SCIENCE AND CONTROLS

Custom-built analytics and quality control to increase your efficiency

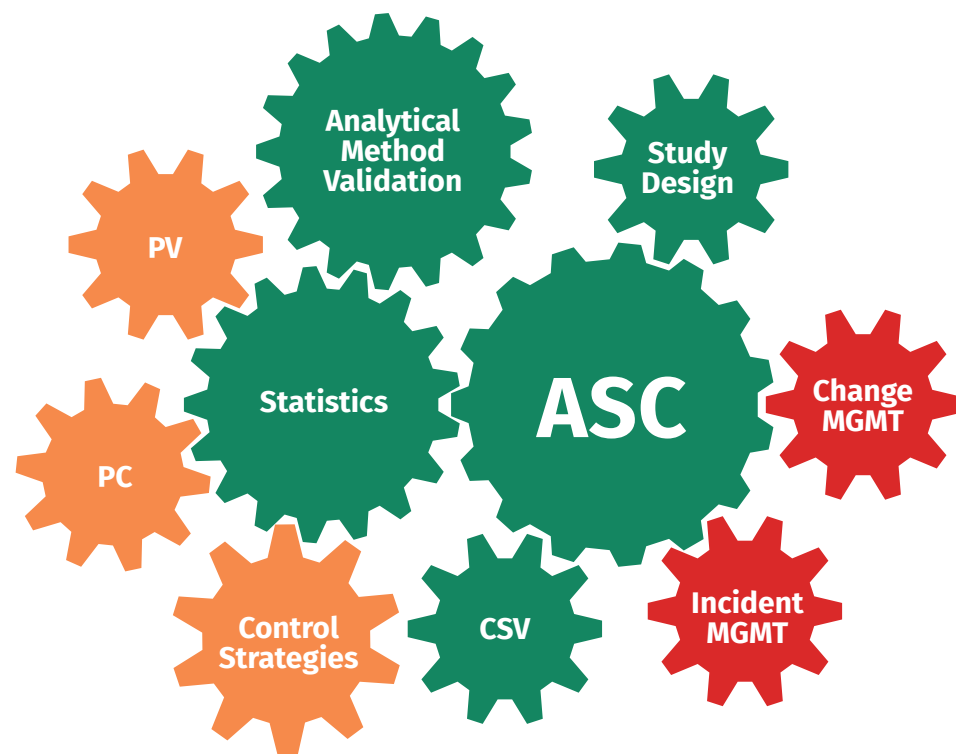
vtu.com

ANALYTICAL SCIENCE AND CONTROLS

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This is us:

VTU Analytical Science and Controls has specialized in the analytical requirements of the pharmaceutical industry. Our scientific team has extensive project experience in GMP laboratories and analytical development in a regulated environment. With our state-of-the-art analytical, regulatory, statistical and scientific expertise, we support our international customers in the implementation of their specific requirements in a targeted as well as timely manner.



This is what we do:

We support you in establishing appropriate analytical methods for your specific process and the according requirements.

In addition, we advise on scientifically and regulatory solid transfer and validation strategies. We offer expertise and hands-on support for all organizational and technical processes related to quality control and analytical development, such as: implementation of new methods, sample management, setup of stability studies, deviation and OoX handling, change management and preparation of inspections.

Our work complies with the requirements of the current pharmacopoeia as well as the FDA/EMA guidelines. We have participated in countless GMP inspections and have an extensive track record of successful product submissions.



Our services:

Establishment of strategies

- Master plans for the implementation, transfer and validation of analytical methods
- Analytical control strategies
- Process control strategies
- Data integrity

Study design and documentation

- Method validation
- Method transfers
- Method verifications
- Comparability and stability studies
- Biosimilarity studies
- Validation of laboratory equipment and computer-based systems

Statistical expertise

- Evaluation and comparison of data and trends (e. g. comparability)
- Definition of limits for process control strategies, process validations and specifications

Project management and technical coordination

- Analytical transfer management
- Analytical development lead for CMC projects
- Digitalization projects
- Inspection preparation
- Sample logistics and storage

Preparation of assessments, SOPs, regulations and reports

- Comparability and stability studies
- Assessing compliance with pharmacopoeia updates
- Data integrity

Preparation and management of authority inspections

- Gap analyses
- Subject catalogues for the preparation of inspections
- Creation of storyboards
- Organizational support during authority inspections

Digitalization

- Analysis of your status quo and development of digitalization concepts
- Implementation of laboratory robots
- Sampling automation
- PAT – methods and validation
- Smart reporting solutions
- Data integrity consulting
- Validation of computerized systems

Your benefits:

Proven quality:

- Individual solutions
- Scientifically sound concepts
- Smooth transition across all project phases

Successful projects:

- Efficient method validations and transfers
- Successful inspections and regulatory filings

Increased profitability

- Optimal usage of resources at peak times with high workloads and understaffed departments

Punctuality and variability

- Reliability and flexibility through on-time planning and (individually) adaptable staff allocation that is tailored to your needs

Your contacts:

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