



Building Quality into Products

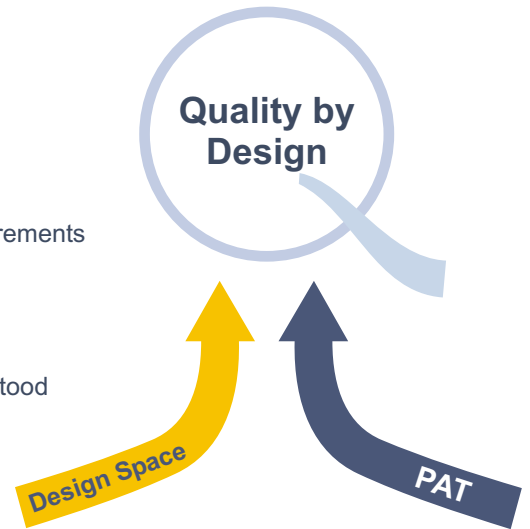
**Quality by Design (QbD) and
Process Analytical Technology
Solutions**



“ Quality cannot be tested into products, it should be built in, or by design ”

Why Quality by Design (QbD) ?

- The API / drug product is designed to meet patient needs and performance requirements
- Critical sources of process variability are identified and controlled
- Appropriate control strategies are developed
- The process is designed to consistently meet critical quality attributes
- The impact of starting raw materials and process parameters on quality is understood
- The process is evaluated and updated to allow for consistent quality over time

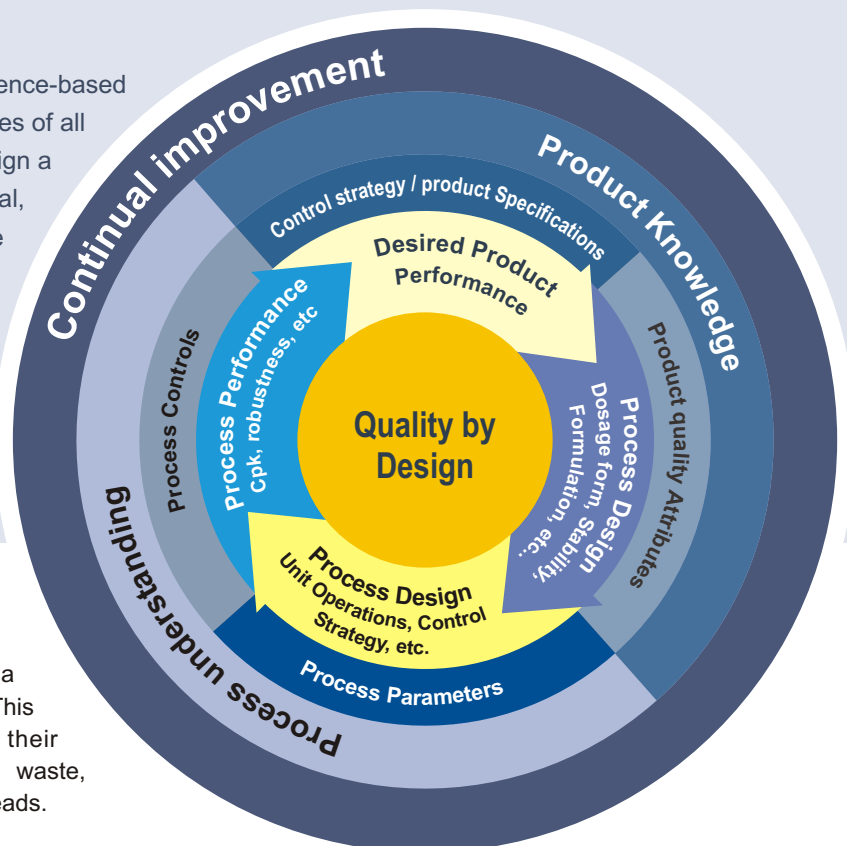


“ Quality by Design is the overarching paradigm.

Design Space and PAT are tools to achieve this ”

Effective PAT implementation is founded on detailed, science-based understanding of the chemical and mechanical properties of all elements of the proposed drug product. In order to design a process that provides consistent product, the chemical, physical, and biopharmaceutical characteristics of the drug and other components of the drug product must be determined. Although the science of analyzing for chemical attributes such as identity and purity is mature, certain physical attributes such as solid form, particle size, and particle shape are more difficult to analyze and control.

With over 20 years of experience, CAMO is the market leader in supplying a complete range of Multivariate Analytical solutions which can provide industry with a smooth, risk-free transition to the application of PAT. This strategy allows customers to naturally increase their understanding of processes resulting in reduction of waste, improved manufacturing cycle times and less factory overheads.



Quality and Process Understanding Expertise



Strategy development

- Development of Quality by Design (QbD) and Process Analytical Technology (PAT) strategies
- Implementation of QbD and PAT strategies
- Systematic approach for Process Optimization, achieving Process Understanding using PAT and Six Sigma

Management adoption of strategy

- Development and documentation of strategic and financial benefits
- Why to Do / What to Do / How to Do - implementation of strategies
- Presentations and Documentations
- Change Management - strategic changes in Pharmaceutical manufacturing using PAT



Technology

- Selection of relevant Process Analytical Technologies for different applications
- Infrared (IR) and Near Infrared Spectroscopy (NIR) - theoretical training
- Theoretical and experimental implementation of spectroscopy
- Training and Implementation of DoE (Design of Experiment) and Multivariate Analysis (MVA)

Implementation / Delivery

- Introduce the PAT concept to new users
- Applying PAT Guidelines and standards
- Set up of implementation system
- Search and selection of key people with core competences
- Specify and agree key assignments for those who drive implementation
- Coach PAT project management
- Monitor and review of implementation



Project Examples

- PAT and QbD project management
- Implementation and improvement of process control with multivariate analysis
- At-line Process Control Using a NIR Spectrometer
- Chemometric Analysis of Imaging Data
- NIR Raw Material Identification
- Development of NIR Moisture Control
- Development of Novel Technology for Drug Evaluation on Medical Device
- Scientific Instrumentation Market Analysis
- Statistical and Chemometrics Training
- Spectroscopic and Chemometric Analysis of Raw Material, In-Process and Finished Drug Products and Medical Devices

Quality by Design (QbD) and Process Analytical Technology Solutions

About CAMO ASA

CAMO ASA is a pioneer in scientific software, workflow management and IT services company that is publicly listed in Norway OTC. Our Multivariate Data Analysis and Chemometrics engine, The Unscrambler[®], offers the most definitive analytical modeling, prediction and optimization solutions.

Headquartered in Oslo, Norway, CAMO's passion is the comprehension and simplification of complex data, resulting in efficient identification, cost, research and design, as well as faster analytical results. This allows our clients to provide an accelerated return on investment in research, development, manufacturing and business.

Products

The Unscrambler[®]

Multivariate analysis & Chemometrics

Unscrambler Online

Online Prediction & Classification

Unscrambler Optimizer

Product Formulation & Process Optimization

OEM Products

Unscrambler Predictor (OLUP)

Online Prediction

Unscrambler Classifier (OLUC)

Online Classification

Training

Multivariate Data Analysis (2 days)

Design of Experiments (2 days)

Multivariate Analysis Of Spectroscopic Data (3 days)

Multivariate Analysis of Sensory Data (3 days)

(Public Training & Inhouse customized training)

Professional Services

We comprise over hundred years of combined experience in Multivariate analysis, Chemometrics and PAT solutions for Pharmaceutical, Chemical, Oil & Gas and Food & Beverages. Our array of solutions stems from one-on-one listening and consulting. We provide complete consulting services including workshops, seminars training, webinars and on-site technical support.

Customized Solutions

New Product Development

Product Integration

Data Migration & Quality

(Offshore Development Center in Bangalore, India)

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Consultation!



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