

# Quality Control and Quality Management

. Release analyses . Method development . Method validation  
. Quality management



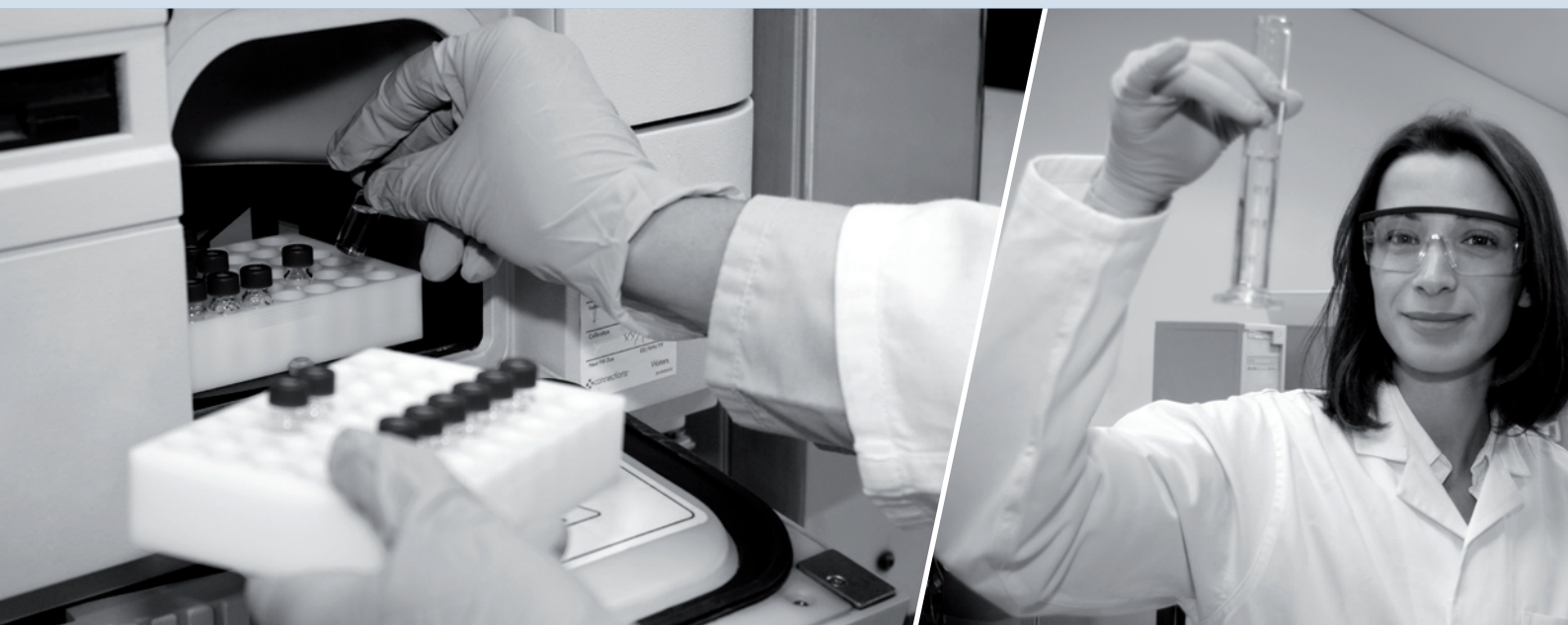
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## Capacity bottleneck

The development and validation of analytical methods require instrumental and human resources which are not available, especially if capacity is utilized to a high degree during routine operation. Frequently, there are also special requirements for equipment and sample preparation (e.g. LC-MS/MS, highly potent APIs, narcotics, etc.) which cannot be met in-house on short notice.

## Time pressure

The analysis of release or stability samples must take place close in time to production or outsourcing and in accordance with standard works (e.g. EP or USP). In many cases a qualified person (QP) is additionally required for batch release.



## R & D and GMP

Quality assurance and quality control in chemical and pharmaceutical environments must satisfy the stringent requirements of both customers and the regulatory authorities. Observance of current GMP regulations ("compliance") is a decisive factor for business success in this context. The task of applying GMP rules during the early phase of development is a balancing act between the goals of flexibility and compliance.

## Technical writing

The task of establishing and updating regulatory affairs documents (e.g. CTDs, IMPDs, INDs) requires a large expenditure of time and binds resources. Short-term bottlenecks occur before and after requests from the regulatory authorities, within the framework of validation and qualification measures, and during approval preparations.

## Reference substances

Qualified reference substances are required for method validation, screening and pharmacokinetic studies. Precisely monitored premises are required for storing reference substances. Sampling, packaging and shipping must conform to the requirements in the medicinal product guidelines.

## Time and cost controls

Customer-oriented project management, regular teleconferences and transparent transmission of information are basic prerequisites for successful services.



## Services

- . Provision of QM and/or QC capacity on demand
- . Performance of release analyses in accordance with EP and USP
- . Provision of consulting services and support for the establishment and expansion of your QM system
- . Planning and execution of method validation and method transfer
- . Statistical data analysis
- . Support during audits and preparations for audits
- . Prompt compilation and revision of QM documents (e.g. IMPDs, SOPs, validation reports, etc.)

- . Compilation of master plans, QM manuals and other documents according to your specifications and in the format you desire
- . Qualification, storage and shipping of reference standards with a GMP certificate
- . Analytical methods for highly potent substances and narcotics
- . Efficient project management

## Analytical methods

- . HPLC (chiral und non-chiral)
- . GC/MS and LC/MSn
- . High-field NMR (700 MHz)
- . IR, UV

- . Wet chemistry methods (e.g. titrations, sulphated ash, etc.)
- . Ion chromatography
- . Heavy metal determination
- . GMP storage and monitored transports

## About us

- . We are a flexible owner-run medium-sized company with short paths
- . We have been providing analytical chemical services for pharmaceutical companies worldwide for more than six years
- . Our team of scientists speaks our customers' language
- . The projects and goals of our customers are our motivation