Case Study

Lifecycle management for drug products

Challenge

Reluctance to compute tolerance intervals

- Needed support with the preparation of Module 3 and corresponding Module 2.3 documents for drug substances and drug products:
  - To reflect the current status of manufacturing process and state of the scientific art analytical procedures
  - To close gaps and achieve GMP compliance of regulatory documentation.
- Required on-going lifecycle management for all drug product licenses needed.

Solution

Authoring of Module 3 and corresponding Module 2.3 documents

- Undertook a gap analysis of current existing Module 3 documentation status versus new authored Module documentation for each license.
- Prepared of country-specific variation packages.
- Provided a single contact point for all CMC related questions and co-ordination of project.
- Compiled, published and submitted variations to respective Health Authorities.
- Responded to Health Authority questions.

Outcome

Approval of variations and subsequent gap closure

- Successful preparation of state of the scientific art Module 3 and 2.3 documents.
- Flexible support for authoring, review and consultation according to client´s needs.