Case Study

Regulatory CMC Compliance Project to reduce product ‘non-compliance’ risk

Support in compliance checks and following activities

Challenge

8 medicinal products, involving 50 MAs, registered across 20 markets

- Identified deficiencies in Change Control procedures and GMP manufacturing documentation
- Uncertainty in verifying the current registered information held with Health Authorities
- Lack of Regulatory Information Management (RIM) systems and therefore lack of oversight of product information for key stakeholders

Solution

Project manager and experienced team of up to 6 FTE engaged on project

- Retrieval of current registered documentation for medicinal products in local markets and equivalent GMP manufacturing documentation
- Gap analysis performed and understanding of product risk in each market determined
- Development of appropriate Change Control System for both labelling/artwork and CMC changes
- Redesign of GMP manufacturing documentation
- Preparation and submission of variation packages to close compliance gaps
- Follow-up of variation submissions (RFI responses) through to approval

Outcome

Product ‘non-compliance’ risk significantly reduced across the medicinal products in the markets

- Efficiencies gained in manufacturing processes and closer links established to Regulatory Affairs function
- Increased visibility of proposed changes and robust Change Control System now established
- Organization able to incorporate in future mechanisms for “sustained” compliance

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