

CASE STUDY

Quality & CAPA Management

During Marketing Authorization Holder Transfers

Visual Snapshot

Background/Project Overview

- **Product Portfolio:** 6 Medicinal Products, 3 of which are Drug Device Combination (DDC) product with biologics
- **Services Provided:** Local QPPVs, Local literature screening, PV Consultancy in LATAM region
- **Territories Covered:** 33 total including LATAM, APAC (Singapore), EEA, USA & Canada

33
countries
worldwide

Challenge

Challenge 1:

Previous Client's MAH in Product Portfolio
(6 Medicinal Products, 3 of which are DDCs with biologics LATAM region had numerous critical inspection findings)

Challenge 2:

Product license was at risk during MAH transfer due to potential delays e.g. addressing timely regulators' requests

Challenge 3:

New DDC product MA Application was put on hold due to inspection findings and MAH transfers

Approach

- **Gap Analysis:** Review of CAPAs and historic information, identification of issues and proposal of corrective preventative actions. Development of Transition Plan and Project Set-Up Plan with the purpose to ensure there is no loss of safety data and that business continuity in local activities are maintained during transition period of changing PV responsibilities.
- **Process Improvements:** Provision of PV training and support in development of processes to fill process gaps and ensure compliance, delivering training to client personnel – process testing, client and agency audit. Assisting in development of local PSMF in alignment with regulatory frameworks. Integrated local country specific PV plans into global plans.
- **Facilitate Communication:** Between the outgoing and incoming MAHs and with agencies and managed MAH Transfer in time and seamlessly continued marketing placement.
- **Flexibility:** Offer the level of support required, e.g., long-term assignment, specific qualification or therapeutic background, deputy services, interim solution whilst developing in house capabilities or facilitating timely MAH Transfers.

Result

- Inspection findings successfully addressed and appropriate actions put in place.
- MA successfully transferred to new MA holder and license was maintained.
- New DDC product MAA successfully submitted and approval obtained.