

# Harmonisation Helps

As a small UK-based pharmaceutical company developing a single (currently unlicensed) biological product, Daval has faced a litany of decisions regarding the outsourcing of many of its core activities

These activities range from caprine serum collection, through the manufacturing and vialing process, to the design and monitoring of clinical trials. At present we have regulatory and clinical advisors working with us in 6 countries. These span the jurisdictions of the vital trio of the FDA, EMEA and TGA as well as the associated veterinary medicine authorities. Were it not for the success in recent decades of various international harmonisation initiatives, this would have been an entirely unworkable platform for development of a complex medication.

At first, regulatory hurdles seemed insurmountable. Our novel production process involves a major reliance on cold-chain (at

minus 20 degrees C) handling. Not only does this produce challenges within the rules of cGMP (current good manufacturing practice), but advanced validation of components such as seals, filters and conduits requires particular attention even when they are standard items in more conventional processes. In addition, the absolute priority of patient safety necessitated the adoption of rigorous approaches to ensuring prion and viral safety. For example, serum acquisition had to be transferred to Australasia from North America and major studies have required initiation with respect to virological matters.

Harmonisation of standards across these geographical regions has meant that prod-

uct components and finished medication can pass smoothly between them and that importantly, documentation of appropriate provenance in one country will tend to be respected in another. This practice is backed up by mutual upstream and downstream auditing at the respective sites and regular inspections by the competent authorities.

It is my own view that further progress can be made in the realms of Marketing Authorisation applications and Orphan Drug designation, but much has been achieved. ●

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