Seminars on Good Manufacturing Practice (GMP) - Quality Assurance & Quality Management

- February 2012 -

PROGRAM (Draft)

Topics:

APVMA Audits: getting better outcomes

- Engaging an auditor: selection of the most appropriate auditor, negotiating realistic audit scope and duration
- Preparing the facility for audit: planning (utilising internal audits), reviewing changes
- The audit and exit meeting: understanding number and nature of non-conformances reported
- Corrective actions: importance of addressing root causes behind non-conformances
- Audit closure and regulatory review.

Quality Assurance and Risk Management

- APVMA requirements and expectations
- Elements of Quality assurance
- Knowing your product and identifying critical processes
- Quality assurance of starting materials: specifications; selection, approval and audits of suppliers; testing; Cs of A.
- Validation (general) : complying with requirements and using it to your advantage
- Validation of computer generated documents and processes
- Water and environmental monitoring
- Stability programs
- Personnel and training
- Contract manufacture and GMP Agreements: the importance of due diligence
- Release for supply: responsibilities and pitfalls

Overseas GMP

- Overview of the Overseas GMP Scheme
- Submitting the correct evidence: recent developments in Europe
- Audit process: useful tips for minimising this cost of 'business'
- Imported actives

Q&A

- ***Participants are encouraged to submit any questions to the APVMA (mls@apvma.gov.au) by the 30 January 2012.***