

Seminars on Good Manufacturing Practice (GMP) - Regulatory & Technical Aspects

- February 2009 -

PROGRAM

Registration **8.30am**

Introduction **9.00am**

GMP CODE REQUIREMENTS / TECHNICAL ISSUES (Mr Ian Wheatley) 9.05am

- Quality management
- Risk assessment / risk management
- Validation master plan
 - equipment
 - cleaning
 - process
 - computers

Morning Tea **10.30am**

- Quality assurance
 - change control
 - internal audits
 - contractor and supplier audits
- GMP agreements
- Sterile products - special considerations
- Questions

12.15pm

LUNCH **12.45pm**

REGULATORY / OPERATIONAL ASPECTS (APVMA) 1.15pm

- GMP Section Update
- Audit process – timeframes, closure of audits, scheduling of audits, risk assessment
- Non-conformances - Original code vs revised code
- Audit timeframes and auditor performance
- Manufacturer feedback - summary
- Release for supply – what this really means
- Compliance with licence conditions (standard and “special”)

Afternoon Tea **3.15pm**

- Relocation of premises – manufacturers’ obligations, and audit requirements
- Change of ownership of business/facility – manufacturers’ obligations, and audit requirements
- Other Recognised GMP Accreditation (eg TGA, NATA)
- Licence updates – when, why
- Overseas GMP Scheme: update, outcome of review
- Export certificates
- Questions

4.30pm

CLOSE **5.00pm**