Use of Veterinary Vaccine Production Facilities For The Production of Human Vaccines within the EU

David Mackay
Riccardo Luigetti
Veterinary Medicines and Inspections Unit
EMEA, London
Requirements for Manufacture/Import

- Manufacturing Authorisation required to manufacture immunological medicinal products within the EU in line with Directives 2001/82&3, as amended
- Authorisation issued by Member State in which the product is manufactured (or imported)
- Authorisation specifies manufacture of products for human use, veterinary use or both
- Change of use will require a variation or a new authorisation
- 30 or 90 day procedure with optional inspection by the National Competent Authority
Good Manufacturing Practice

- Single EU GMP Guide for both human and veterinary medicines
- GMP requirements the same for both types of product
- Highest risk for live products is of contamination of product or starting material with another live organism
- Vaccines for human use involving growth of organisms usually produced in dedicated areas
- Other products produced on a campaign basis with suitable decontamination
Good Manufacturing Practice

- Annex 2: Manufacture of Biological Products for Human Use
- Annex 5: Manufacture of Immunological Veterinary Medicinal Products
- In veterinary facilities work on a campaign basis is common
- ? NCAs may require dedication of facilities for duration of production of human vaccines ?
Good Manufacturing Practice

- ICH Q9 document ‘Quality Risk Management’: final text agreed by ICH partners
- Q9 will be added to the EU-GMP guide as annex 20
- Q9, particularly Annex II.4; ‘Quality Risk Management for Facilities, Equipment and Utilities’ and Annex II.6; ‘Quality Risk Management as Part of Production’ useful to assess risks of use of veterinary facilities for human vaccine production and need for dedicated facilities
Other requirements

- Type II variations to Marketing Authorisations of relevant products
- Training of personnel and production of appropriate documentation (SOPs etc)
Conclusions

• There are no substantial impediments to the use of veterinary vaccine production facilities for the production of human influenza vaccines within the EU