

Nexus SME Toolkit

An introduction to GxP requirements (GMP/GLP/GCP/GDP)

Delivered by
Edwin Lindsay, Principle Consultant,
Compliance Solutions (Life Science) Ltd

In the first of a series of seminars targeted at addressing issues facing SMEs, this seminar introduces and explores GxP requirements, demonstrating that a common sense approach can help both SMEs and large organisations to ensure they remain compliant.

Sponsored by

Burness 

Thursday 23 July, 2009
Burness LLP, 120 Bothwell Street, Glasgow, G2 7JL

This event is free, however, places are limited.
To reserve your place, please complete an on-line
registration at www.nexxusscotland.com/events

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Nexxus SME Toolkit

This **nexxus** SME Toolkit seminar will be presented by Edwin Lindsay, Principal Consultant of Compliance Solutions (Life Science) Ltd.

Companies in the pharmaceutical, biotechnology and medical device industries are constantly pushing the boundary of innovation to develop new products. In coping with this 'bleeding edge' innovation, compliance with the regulatory requirements is becoming far more rigorous, challenging the industry to meet the constantly rising standards of quality and compliance.

Nexxus is pleased to present an introduction to GxP requirements to demonstrate that a common sense approach can help both SMEs and large organisations to ensure they remain compliant. Topics covered in the seminar include:-

- Basic steps to compliance with GxP (GMP/GLP/GCP/GDP)
- Increasing regulatory requirements for all organisations (including the NHS)
- Approach to an MHRA/FDA audit
- Even the big companies fall foul of the regulatory authorities, ie Coca Cola

Programme

Registration/Sandwich Lunch 12.00 - 12.30pm

An introduction to GxP requirements 12.30 - 1.30pm

Edwin Lindsay, Principal Consultant of Compliance Solutions (Life Science) Ltd

During the past 13 years Edwin has developed proven expertise in regulatory, quality and validation disciplines in the Pharmaceutical, Biological and Medical Device industries and is experienced in the preparation of new and amended European (CE Marking) and US FDA Regulatory (510K, PMA, IDE) submissions, development and implementation of quality systems to ISO 9001, ISO 13485, GMP/GLP and the US FDA Quality system regulations.

Edwin's current clients include Scottish and Northern Ireland National Blood Transfusion Services, Tayside Flow Technologies, Cambrex, Ventana Medical, Integra Life Sciences, American Red Cross, Novartis, Optos and Oracle.

Question and Answer Session/Networking 1.30 - 2.00pm



Nexxus is currently funded by the European Regional Development Fund and a number of Scottish organisations - see website for full details.

