phss
over 25 years of advancing pharmaceutical and healthcare sciences

PHSS-UCL Q3P Annual Conference 2017

8th September 2017 | UCL School of Pharmacy London UK

Challenges in Biological and Advanced Medicinal Therapeutic product manufacturing following GMP.

This major PHSS conference will address the key challenges in manufacturing Biological and Advanced Medicinal Therapeutic products (ATMPs) considering challenges in GMP compliance.

New biological products present new challenges in aseptic processing, contamination and cross contamination control at many different scales of processing. The conference considers the significant trend in change from traditional pharmaceutical 'Block buster' products, produced mainly by chemical synthesis, to developing biological products that employ more effective biological delivery mechanisms and interactions. Biological synthesis not only presents challenges in GMP, but process and patient risk profiles are very different to traditional pharmaceutical sterile product manufacturing, particularly considering new challenges in personalised medicinal therapies.

This conference presents the changing scene with significant advances in medicinal and therapeutic products together with a GMP inspector's point of view on the challenges of GMP Compliance. In addition there are two presentations that cover facility design for biological product manufacture and Quality assurance in preparation of personalised Cell therapies.

Not a conference to miss to keep up with new biological product and medicinal therapeutic product development that now have the additional challenge of compliance to the revised EU GMP Annex 1.

Please support the Exhibition with exhibitors who can provide further knowledge and support with technologies and essential supplies/ services in sterile product manufacturing.

International attendees are encouraged to engage with the challenging area of risk based GMP, new biological product and Therapeutic products developments together with European regulatory perspectives and interaction with industry key opinion leaders and Subject Matter Experts.

FREE TO PHSS MEMBERS

PHSS-UCL Q3P Annual Conference 2017

8th September 2017 | UCL School of Pharmacy London UK

PROGRAMME: Challenges in Biological and Medicinal therapeutic product manufacture to risk based GMP

Registration from 8.30am

9.15am
PHSS and UCL School of Pharmacy/ Q3P welcome and overview of conference sessions.

9.30am - 10.15am
Key note presentation: The changing Pharmaceutical industry with a significant transition from traditional 'Block Buster' pharmaceutical products to more biological products that require specialised manufacturing. New biological products are often manufactured at smaller scale where themes of process modularity, scalability and flexibility are developing to support a new world of diverse products including biologicals, Cell/ Gene therapies and personalised medicines with new innovative delivery mechanisms and devices.

Speaker: Gert Moelgaard Senior Consultant at Moelgaard Consulting, Denmark. Past Chairman of ISPE. Past Vice President of NNE Pharmaplan. Board member Vetter-Pharma Fertigung GmbH. DTU Technical University of Denmark.

10.15am - 11.00am
Challenges in Biological and Advanced Medicinal Therapeutic (ATMP) product manufacture with GMP Compliance: A GMP inspectors point of view.

This presentation will consider GMP regulatory guidance and key messages from regulatory authorities on revisions and regulatory expectations.

11.00am - 11.45am
Coffee, networking and viewing exhibition.

11.45am - 12.30pm
Presentation: Considerations in Facility Design for biological product manufacturing and Medicinal Therapeutic product manufacturing. The presentation considers Process scalability, modularity and flexibility together with balancing requirements for GMP and Biological safety. Speaker: Consultant: TBC.

12.30pm - 1.30pm
Lunch and viewing exhibition, exhibitor demonstrations.

1.30pm - 2.15pm
Presentation: Quality Assurance and GMP compliance in Cell therapy processing for personalised medicines. Speaker QA manager Cell therapy facility (TBC).

2.15pm - 2.45pm
PHSS Guidance update; Environmental Control and Process Monitoring Case study guidance initiative together with Clarity in GMP on challenging topics. Status update by James Drinkwater Leader of PHSS Bio-contamination Special interest group and Focus groups.

2.45pm - 3.00pm
Short afternoon break.

3.00pm - 4.00pm
Discussion session: Revision of EU GMP Annex 1. Key points from draft review and comments put forward by the PHSS Annex 1 revision Focus group.

EU GMP Annex 1 revision will impact all in pharmaceutical medicinal product and Advanced Therapeutic Medicinal Product manufacturing. There will be issues to discuss as the new draft has increased to around 50 pages accommodating new products, new technologies and new practices – an important discussion to be involved in, so all perspectives can be considered.

Discussion Facilitator: TBC

4.00pm
PHSS Chairman's thanks and closing remarks.

TO BOOK VISIT phss.co.uk/events

FREE TO PHSS MEMBERS