Biorisk Management Workshop

Singapore, 5 – 6 January 2018

Overview

This one-and-a-half-day course is designed to provide an in-depth discussion of current biosafety and biosecurity principles and practices. The course is suitable for all levels of experience, including safety professionals, managers / supervisors, engineering personnel and those responsible for compliance and oversight. The course is predominantly based around requirements contained within the WHO Laboratory Biosafety Manual, with examples also taken from GAPIII (WHO Global; Action Plan to Minimize Poliovirus Facility-Associated Risk[1]), as examples of current documents of relevance to vaccine manufacturers (note: the course is not polio-specific, GAPIII is simply being used to illustrate current thinking and as an applied example).

On day one presentations will be made on the emerging regulatory environment regarding work with potentially high-risk pathogens and how this may continue to evolve in coming years. The morning of day two will be broken into two sessions, one focussing on containment-relevant engineered systems (e.g. HVAC, kill tanks, etc.), followed by a session discussing how to establish and effective management programme and team, including identification of key roles and responsibilities. During the afternoon of day two small groups will be formed to discuss specific areas relating to the previous sessions, where company-specific examples of current issues and challenges can be discussed, before presentation of potential solutions to the wider group. Participants are encouraged to supply examples of potential focus areas to DCVMN in advance of the course in order to help with preparation of the session.

The course is designed to be highly interactive, providing an overview of both basic principles and specific areas of concern to vaccine manufacturers. Course materials include a set of handouts and interactive exercises to illustrate specific principles and stimulate discussion.

Course presenter

The course presenter is Dr Paul Huntly, Managing Director of Riskren, specialising in risk assessment and management associated with biorisk management (biosafety / biosecurity), infection control in healthcare, and in particular areas concerning GAPIII, addressing measures associated with poliovirus eradication and containment. Paul has provided consultancy advice on biorisk and conducted audits and assessments for a variety of organisations, including the WHO, DCVMN, China CDC, the American Society for Microbiology (ASM), A*STAR (Singapore), the Swedish National Institute for Infectious Disease Control, the Canadian Science Centre for Human and Animal Health and several vaccine manufacturers around the world. A microbiologist by training, Paul has specialised in a management systems approach to managing biological risk, and developed the concept that led to publication of CWA 15793:2008 - Laboratory Biorisk Management Standard, together with the DNV Managing Infection Risk Standard (2012). Paul is based in Singapore, but works extensively throughout Asia and the rest of the world.

[1] http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/GAPIII_2014.pdf

Course Schedule

Day 1 – 5 February (pm)

1330 – 1400 Background and introductions

1400 - 1530 Overview of biosafety, biosecurity and containment principles

1530 – 1545 **Break**

1545 -1700 Current and evolving standards, regulations and oversight mechanisms - WHO LBM, GAPIII and TRS 926

Day 2 – 6 February

0900 – 1030 Overview of facility-related containment principles and issues

- *Primary, secondary and tertiary containment*
- *HVAC*
- *Kill tanks*
- *Autoclaves, pass-throughs and dunk tanks*
- *Room decontamination and shutdown strategies*

1030 – 1050 **BREAK**

1050 – 1230 Overview of biorisk management system-related principles and issues

- *Developing an effective programme*
- *Identifying and incorporating requirements*
- *Policy and leadership*
- *Key roles, recruitment and competency*
- *Integration with QMS, GMP, etc.*
- *Managing emergencies and incidents*
- *Biosecurity*
- *Review, oversight and certification*

1230 – 1330 **LUNCH**

1330 – 1500 Small group discussion on practical issues and challenges

1500 – 1515 **Break**

1515 – 1630 Presentation and problem solving with open discussion

1630 – 1700 Q&A and Conclusions

Recommended reading prior to the course

1. WHO Laboratory Biosafety Manual (2004)
   http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf
2. CWA; Laboratory Biorisk Management (2011)
   ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf
3. GAPIII - WHO Global; Action Plan to Minimize Poliovirus Facility-Associated Risk http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/GAPIII_2014.pdf

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