Developing a competency profile for professionals in medicines safety – safety scientists

Hans H. Lindén [1,2] and Claire Johnson [3,4]
1 EUFEPS, The European Federation for Pharmaceutical Sciences; 2 SafeSciMET; 3 EMTRAIN; 4 European Bioinformatics Institute (EMBL-EBI) European Molecular Biology Laboratory, Hinxton, Cambridge, UK

In order to keep pace with big and small pharma industry-wide changes, and be able to apply up-to-date and new scientific achievements to drug/medicines research and development, scientists and other professionals need to continually develop their competence, and be able to provide evidence to support it. A 'new breed' of safety scientists has been asked for, and it is emerging; not the least underpinned by recent and on-going IMI (Innovative Medicines Initiative) research, education and training projects. A deliverable of IMI-TRAIN WP3 is to develop a competency profile for safety scientists.

Development phases include pre-clinical testing of new active and other components of medicines and safety prediction into human, safety evaluation of new products in clinical testing on healthy volunteers and patients with targeted diseases, male and female, young and old, and post-approval usage and pharmacovigilance of medicines having been approved for use by the regulatory agencies. General understanding of how the safety aspects are holistically seen to in the different phases, in cutting-edge drug discovery and development processes, and in the full lifecycle of a medicine, is required, as is, not the least, specialist and expert insight into many scientific disciplines and the integration of them.

Through a task force of members, IMI-Train is developing a competency profile which will support the recruitment, training and development of high quality safety scientists. As a starting point, we are gathering relevant information from publications, syllabi from academic and other postgraduate courses, and requirements of professional bodies. In this, we seek input from experts in all phases of the life-cycle of medicines, from early phases in industrial drug design over the clinical and regulatory evaluation into the use of medicines and devices in health care systems. As we will have arrived at a first draft of the competencies needed in safety sciences, a workshop will be set up to review it and arrive at a preliminary competence profile or profiles, to be finalised in a Delphi study approach, bringing in a wider audience of specialists, experts and relevant professional bodies.*

* Members of the IMI-TRAIN Safety Sciences Competencies Task Force: Hans H. Lindén, Claire Johnson, Cath Brooksbank, Philippe Detilleux, Annie Fourrier-Reglat, Shirley Price, and Peter Stonier

SAFETY SCIENCES COMPETENCY PROFILE

Who are Medicines Safety Scientists?

Those engaging in systematic activity for sciences-based drug/medicines safety in all phases of medicines research and development. These professional require insight into many scientific disciplines and integration of them, as well as implementation of holistic and translational perspectives.

What is Safety in Medicines Development?

Efficacy, quality and safety are key elements in arriving at new medicines. Development phases are:

- pre-clinical testing of new active and other components of the product worked on and safety prediction into human,
- safety evaluation of new products in clinical testing on healthy volunteers and patients with targeted diseases, male and female, young and old, and
- post-approval usage and pharmacovigilance of medicines having been approved for use by the regulatory agencies.

Starting material

Relevant information is being gathered from a number of sources including publications, syllabi from academic and other postgraduate courses, and known requirements by professional bodies.

- Syllabus, learning outcomes and competencies described within the SafeSciMET programme (European Modular Education and Training Programme in Safety Sciences for Medicines); www.safescimet.eu
- Relevant sections of the syllabus, learning outcomes and competencies described within the Eu2P programme (European programme in Pharmacovigilance and Pharmacoepidemiology); eu2p.org
- PharmaTrain/IFAPP core competencies: drug safety surveillance domain
- PharmaTrain e-learning programme video on drug safety
- The IMI-2 Strategic Governing Group (SGG) on “translational safety”
- Publication from International Society for Pharmacoepidemiology: Pharmacoepidemiology: defining the field and its core content; Pharmacoepidemiology and Drug Safety (2012); 21: 677–689
- Publication: Teaching Pharmacovigilance: the WHO-ISoP Core Elements of a Comprehensive Modular Curriculum; Drug Safety (2014) 37:743–759
- EUROTOX Competencies for European Registered Toxicologists

Next steps

- A workshop will be set up to review and bring it all together into a draft document – to be reviewed and finalised with a Delphi study approach among a wider audience of specialists, experts and professional bodies.
- IMI-TRAIN WP3 will address implementation of the competency profile for safety scientists and exploring a CPD accreditation body for European registration