

Achievements and challenges in the implementation of lifelong learning for the regulatory profession



Summary

As a signatory to the agreed LifeTrain principles for professional bodies, TOPRA is taking steps to encourage regulatory professionals in ALL sectors to maintain competence, both technical and professional, by providing the tools and the framework to do this. A communications exercise is needed to persuade this sector of the value of this both personally and to the product development process.

Introduction

TOPRA is the professional association for those involved in healthcare regulatory affairs in the human, device and veterinary sectors. Members come from over 50 countries and from diverse sectors, including industry, agency, support companies and consultancies.

TOPRA has been a signatory to the LifeTrain agreed principles for Professional/Scientific Bodies since 2013.

EXPLORING

- Those wanting to take their first step in regulatory
- Those in other disciplines who need an overview

Up to 6 months' experience

ESTABLISHING

- Those who have recently joined the profession
- Those whose regulatory experience is outside the EU

6 months'-2 years' experience

CONSOLIDATING

- Experienced professionals committed to developing their regulatory and management competencies

2-5 years' experience

DRIVING

- Those at a senior level taking on additional responsibilities or looking to diversify their skills

5+ years' experience

INFLUENCING

- Discussion, debate, and networking opportunities for senior professionals

8+ years' experience

Challenges

- Regulatory Affairs is a 'non-regulated' profession; there is no requirement to demonstrate professional qualification to practice
- Regulatory Affairs is a 'secondary' profession: many specialists are primarily qualified in another discipline (chemistry, biosciences, pharmacy), which require evidence of competency to be maintained for 'registration'. Further requirements are therefore onerous
- The nature of the regulatory profession is one of rapid change and continual updating of knowledge – professionals do this 'for the job' and do not always view it as 'personal development' – and have a crucial role in delivering innovation from discovery to bedside
- Due to the diversity of the role, competences are also highly diverse, and regulatory professionals in industry and agency have complementary competences.

Achievements to date

Membership

- TOPRA encourages maintenance of professional competency as a prerequisite to membership grades that carry a post-nominal (M TOPRA), expecting between 50-100 hours of 'CPD' per annum should be carried out. Data are collected on CPD hours at each annual renewal
- TOPRA has a lifelong learning scheme that allows for members to record their CPD with TOPRA if they wish: many however are already doing this for employers and other primary professional societies. This encompasses the 'plan, do, reflect' cycle advocated by LifeTrain
- A communication programme has been carried out to explain the nature of 'CPD' – not simply 'training' but personal development in the widest sense, including volunteering opportunities within TOPRA
- TOPRA encourages professional development linked to peer endorsement via membership grades (eg Fellowship)
- TOPRA believes that CPD is not only about technical knowledge, but personal skills development and professional standards: all members subscribe annually to a Statement of Values.

Training and Education

- TOPRA has developed a career schematic to show how training needs develop throughout a regulatory career (see graphic)

- TOPRA provides a structured programme of training and education. Since 2014 individual training offerings have been colour-coded to demonstrate more clearly how they link to the career stages. These stages also link to TOPRA membership bands and volunteer roles within the organisation
- LifeTrain training standards are applied to TOPRA training courses
- All training offerings come with lifelong learning hours attached
- Feedback forms require attendees to include 'reflective learning' feedback

Community

- TOPRA has developed a competency framework, which is linked to membership grades and sectors – this is a 'work in progress'
- Competency frameworks developed by the Association of Graduate Regulatory Educators (AGRE) in the USA have been mapped to the TOPRA MSc/Masterclass programme (1). The authors concluded: *The TOPRA-related MSc programmes describe learning outcomes that are consistent with the AGRE competencies*
- TOPRA has committed to a link with LifeTrain through regular presence at the Annual Symposium and occasional conference tracks and publications on LifeTrain initiatives.

Future Plans

- TOPRA is investing in the implementation of a new member engagement system which will allow for automatic and direct recording of CPD hours by members
- TOPRA will be extending work on competences to further refine the framework and link it to other related associations and initiatives
- Ongoing communication of the importance of CPD will continue
- Governance changes are planned that will link membership levels more closely with competence and commitment to CPD
- TOPRA will work with other interested parties to ensure that an approach to regulatory competence will be effective internationally and across sectors.

Conclusion

Progress is being made to develop a competency framework for regulatory professionals irrespective of where they work. AGRE authors concluded that *'Graduates of regulatory programmes have a competitive advantage, as they will have many of the skills needed to contribute effectively to an organisation...'*. This message needs to be part of a communications exercise to encourage active CPD recording and regulatory competency development by professionals, and recognition of its value by employers in all sectors.

References

- (1) **Core Competencies Provide Roadmap for Strengthening Regulatory Education**
Sandra Shire, DMD, MPA, Charles H. Swanson, PhD, Daniela Drago, PhD, and Jean E. Feagin, PhD; Regulatory Affairs Focus, September 2014



Courses aimed at those who are **exploring** EU regulatory affairs and who are taking their first steps in the profession. Providing an overview of regulatory affairs (pharmaceutical, medical devices and veterinary medicines), they are also suitable for those working in associated areas, such as manufacturing and marketing, as well as support staff.



Courses aimed at those who are **establishing** a regulatory foundation and who typically have up to two years' experience in regulatory affairs. These include our residential Introductory courses held in Spring and Autumn, and also our Fundamentals of the EU eCTD course.



Continuing Regulatory Education and Development (CRED) courses are a series of one - and two-day interactive workshops to enhance your knowledge in specific regulatory areas. They are suitable for those who are **consolidating** their regulatory competencies (2-5 years' experience).



The CRED+ courses focus on topics in greater depth and at a more advanced level. They are aimed at those with more than five years' experience who are **driving** their regulatory careers.



Masterclasses are 3-day workshops addressing specific regulatory subjects and are suitable for those who are at the stage of **driving** their regulatory career (5+ years' experience). They are available as standalone courses or taken as modules to form the MSc in Pharmaceutical Regulatory Affairs.



Horizons conferences are open to all but are aimed at those who are at the stage of **influencing** the regulatory profession. They provide a forum for discussion and debate on current regulatory topics.



The TOPRA Annual Symposium is a vibrant forum, where representatives of industry and regulatory agencies come together to discuss today's regulatory issues and debate future plans for regulation. The three symposia – pharmaceuticals, medical devices and veterinary medicines – are open to all regulatory professionals.