TOPRA 2020

CHANGE | CHALLENGE | FUTURE

WHAT WILL HEALTHCARE REGULATORY AFFAIRS LOOK LIKE IN 2020?

HOW WILL THE REGULATORY SCIENCE PROFESSION SHAPE THE HEALTHCARE ENVIRONMENT?

WHAT WILL HEALTHCARE REGULATORY PROFESSIONALS NEED TO KNOW AND DELIVER IN 2020?

WHAT ROLE WILL TOPRA PLAY?

TOPRA 2020

Healthcare regulatory affairs faces unprecedented change driven by globalisation, technological and scientific innovation – plus, of course, the impact of political and economic factors.

TOPRA IS INVESTING FOR THE FUTURE

TOPRA is a member-driven organisation. It is committed to supporting the profession as a whole by enabling individual regulatory professionals deliver better, safer healthcare for patients. TOPRA is working with the profession to help drive and embed regulatory excellence to 2020 and beyond.

OUR COMMITMENT

SUPPORT
Supporting our members

EXCELLENCE
Developing regulatory excellence

GLOBAL
Increasing our global reach

INFLUENCE
Providing a neutral forum for discussion, debate and influence

REGULATORY AFFAIRS 2020

What will healthcare regulatory affairs look like in 2020?

BOB CLAY

President of TOPRA and Consultant, Regulatory Science, Drug Development & Business Strategy, Highbury Regulatory Science Ltd

The regulation of healthcare products (medicines, medical devices and diagnostics) has evolved over the past 50 years from a system focused on the review and control of the safety, quality and efficacy of products, evaluated by national regulators; to a prospective science-driven and globally collaborative system. This evolution might be described in three stages: development of regulatory systems, largely based on past experience; international collaboration and developing common standards; and most recently the emergence of regulatory science and regulators supporting innovation.

As we look forward to 2020 and beyond, the rapidly increasing understanding of molecular biology and the genetics of disease leads to personalisation of therapeutics with an integration of medicines and diagnostics. This complex biology and novel therapeutics will present regulators, developers and society with unprecedented challenges in the regulation of healthcare products. The integration of healthcare data and social networking provides huge opportunities in the real world understanding of both common and rare diseases.

The evaluation of post-market safety data is well established; but, the application of real-world evidence to understanding both benefits and risks should facilitate the development of optimised use of both existing and new therapies. Involvement of patients in the development of medicines and regulatory decision-making will reform our approach to medicines regulation. Increased transparency and the availability of data and sophisticated analytical tools will require increased global collaboration between regulators.

While the trends highlighted here are well known, it is likely that we will see unexpected challenges to our regulatory environment and the regulatory professional will need to keep pace with scientific development, societal expectations, communications and leadership skills required to contribute in a rapidly changing environment.

How will the regulatory science profession shape the healthcare environment?

DAVID JEFFERYS

Senior Vice President at Eisai Medical Research and former President of TOPRA

The life science industry has to convince governments and healthcare providers that it is the major contributor, providing solutions to secure affordable and sustainable global healthcare. Today industry is seen as the problem and the driver of unaffordability and unsustainability. Change in healthcare takes time and a realistic timescale is 2025–30.

What are the major challenges? They are the ageing population, managing expectations, affordability and climate change. The last is already influencing global healthcare through mass migration and emergence of new and changing patterns of infective diseases. On a global level, we have seen remarkable achievements through the programme on neglected tropical diseases launched by the global pharma industry with the London Declaration in 2012 and, this year, the launch of the Accelerated Access Initiative , a unique programme involving IFPMA (co-ordinating the pharmaceutical industry), the World Bank and Gates Foundation. This is necessary as we see a disturbing combination of chronic and tropical diseases manifesting with new disease presentations.

In the developed world, sustainability requires focusing on early diagnosis and on disease prevention. Digital health and connectivity should be major drivers of change in healthcare delivery from telemedicine, through to health monitoring, promotion and assistive technologies enhancing home care. Artificial intelligence should be integral to hospitals in 2025–30.

Regulatory science should be the facilitator – the bridge connecting new disciplines into the drug development and delivery system, ranging from early access programmes such as PRIME and Sakigake and onto pull-through development. We should see more shared development using open platforms and crowd funding. In dementia, regulatory science can facilitate the entry of second generation disease modifiers and third-generation cures using gene technology. Regulatory science should also play a prominent role in regenerative medicines and truly personalised immunotherapies.

Regulatory science can enable healthcare systems to meet the challenges of 2020, 2025 and beyond.

REGULATORY AFFAIRS 2020

What will healthcare regulatory professionals need to know and deliver in 2020?

PETER LASSOFF

Vice President and Head of Global Regulatory Affairs, QuintilesIMS

The regulatory affairs environment is rapidly transforming, with many tasks once handled by inhouse experts now outsourced or automated by developing technology with the use of optimised processes. In light of these changes, regulatory professionals need to redefine the strategic value they bring to an organisation and develop or hone new skills to make themselves indispensable for the future.

Three areas will continue to be in demand regardless of technological advancements: project management skills, specific expertise and relationships with regulators.

Project management is now essential across every aspect of the product development and management lifecycle, including regulatory affairs. Regulatory professionals who demonstrate strong leadership and communication skills and can engage stakeholders and manage risks will continue to be in demand. Pursuing project management training, certification and experience will add value to their CVs and career prospects.

While having a thorough grounding in all aspects of regulatory affairs is the baseline, to stay competitive, regulatory professionals need to develop additional specialisms in an area of interest to patients, regulators and other key stakeholders. That expertise can range from therapeutic areas, regulatory subsets (CMC, clinical, etc) and/or technology. Whatever the area, it is important to become an expert by learning as much as possible and demonstrating that expertise through presentations, project participation and stakeholder interaction.

Because regulatory work is still largely localised with respect to agency interactions, this provides opportunities for thought leadership input for staff within their respective organisations. To make the most of these opportunities, regulatory professionals should focus on expanding their relationships with regulators and establish themselves as key liaisons between the organisation and the regulatory bodies.

Change is always challenging, but if regulatory professionals focus on the core value they bring to their employers, they can build a long, successful and rewarding career regardless of their geophysical location.

What role will TOPRA play?

LYNDA J WIGHT
Executive Director, TOPRA

When TOPRA was established it was to give a forum for regulatory professionals to share practical information with each other, so that they could each perform their roles more effectively – this is formally described in the Constitution as part of our 'Purposes':

- ***To establish professional identity and standards for regulatory affairs personnel***
- ***To promote education and science in regulatory affairs***
- ***To advance the professional competency of members.***

In the regulatory world of 2020 so eloquently described by my colleagues these Purposes still stand true; but the way TOPRA will fulfil them in future must adapt to changing times.

Regulatory professionals must be able to adapt to innovative approaches to data collection, analysis and decision-making; they must be confident working in a digital environment yet never lose sight of the importance of networks and relationships.

TOPRA will continue to provide world-class education and training to a clearly defined and internationally accepted competency framework which takes account of the needs of 2020 professionals. We will use the most modern tools available – but will never forget the personal touch. In the changing world order, to have competences which are transferable to different environments and which have been independently verified will be increasingly important. TOPRA will act as the flag-bearer of regulatory standards globally and provide mechanisms for individuals and educators to demonstrate the high standards they have achieved. And we will continue to promote access and diversity in this wonderful profession as it takes an increasingly central and strategic role in healthcare delivery.

SUPPORT

The healthcare regulatory landscape has changed dramatically in the past decade. TOPRA has adapted to the challenges of a fast-moving technological environment and members' changing expectations.

Individuals and businesses now conduct most of their activities online. TOPRA's comprehensive member engagement database and portal allows members to become part of an online regulatory community. This enables members to manage their membership online; interact with their colleagues in Special Interest communities; access resources, such as *Regulatory Rapporteur*; register on courses; and now record their continuing professional development.

As a membership organisation, TOPRA's primary role is to support its members. It does this by investing in its support team which includes a mix of highly experienced regulatory professionals and personnel from a background in association management, who have the skills and experience to provide responsive and relevant services to members. Leading the organisation is the TOPRA Board who are regulatory professionals elected by members with support from many teams of member volunteers involved across all TOPRA activities.

LISTENING TO MEMBERS

TOPRA 2020 is a culmination of members and stakeholders' feedback and suggestions. It sets out broad strategic and practical objectives for the next three years – a time period that will see major political, technological and economic challenges to the regulatory environment in Europe but also across the world.

OUR COMMITMENT

INTEGRATED PROFESSIONAL DEVELOPMENT PATHWAYS

In order to support and promote the development of professional excellence, TOPRA's framework of continuing professional development opportunities for members at all stages of their careers will continue to expand. With transparent signposting of all the qualifications, conferences, courses, eLearning, webinars and networking opportunities members can plan their own career pathway according to their own circumstances.

BESPOKE MEMBERSHIP COMMUNITIES AND OFFERINGS

Whatever a member's specialty or organisation, TOPRA has relevant offerings across a broad-based regulatory community. As TOPRA's online platforms develop, members will shape their own membership offering so that it is truly bespoke.

Asking members for their views and feedback is not an empty exercise and new services are introduced or developed accordingly. Responsiveness to both individual member needs and the demands of a challenging global and business environment ensures TOPRA maintains and builds its relevance in the healthcare regulatory sector.

GOVERNANCE FOR THE 21ST CENTURY

In an increasingly digital environment some aspects of TOPRA's governance arrangements need to take account of the modern demands of 21st century business practices and standards. TOPRA is proposing a number of constitutional changes to help meet members' needs both now and the future – without affecting its underlying principles and Purposes.

EXCELLENCE

TOPRA helps members perform to the highest level and supports their professional development through all stages of their careers. Projects on regulatory competences, educational pathways and professional accreditation have culminated in a clear exposition of all career stages from student to thought-leader.

ATTRACTING FUTURE PROFESSIONALS

TOPRA offers student membership, reaches out to schools and universities and engages students in TOPRA activities, such as presenting a poster at the Annual Symposium.

In a drive to widen access into the regulatory profession, TOPRA is taking a lead in the UK Apprenticeships Initiative by developing a Regulatory Affairs Standard – that will also be of value to help benchmark regulatory training internationally.

DELIVERING REGULATORY QUALIFICATIONS

TOPRA's postgraduate programmes have seen hundreds of regulatory professionals achieve a worthwhile qualification – from certificate, to diploma or MSc Regulatory Affairs.

A new flexible MSc RA with additional module choices is now available. Students will be able to specialise in either pharmaceutical RA or Medical Devices RA – or combine modules from both specialties, meeting the growing need for regulatory training in drug-device combination products.

Sound research is a driver for any scientific sector – and regulatory science is no different. TOPRA now offers an opportunity to study at PhD level and contribute to the body of regulatory knowledge.

OUR COMMITMENT

RECOGNISING REGULATORY EXCELLENCE ON A WORLD STAGE

TOPRA raises the profile of healthcare regulatory affairs across the healthcare sector, across society and across the world – with the prestigious Awards for Regulatory Excellence Programme, which was established in 2010.

Each year the Programme receives nominations from all over the world – from Cuba to Australia, from Finland to South Africa; from individuals and teams based in agencies to industry, from big pharma to SMEs, from academics to NGOs; and representing all regulatory specialties, including medical devices and veterinary medicines.

SETTING PROFESSIONAL STANDARDS

TOPRA's Statement of Values, signed up to by all members, is at the core of all activities. The public rightly expects healthcare regulatory professionals to work to high standards. TOPRA engages with a wide range of stakeholders, particularly patient groups, to enable access to innovative medicines and treatments in a timely, effective and safe way that meets patients' needs.

TOPRA offers regulatory training accreditation to universities and other providers as well providing accredited bespoke face-to-face or online training to organisations available on an international basis.

FACILITATING PERSONAL ACCREDITATION

TOPRA is building on its continuing professional development offering to support and prepare regulatory professionals throughout their career.

TOPRA is refining its framework of competencies reflecting levels of practice so individual professionals can use it evaluate their performance – and identify their CPD needs in order to move onto the next level.

By 2020 members will access a comprehensive range of personal accreditation opportunities that will extend beyond national borders.

GLOBAL

TOPRA welcomes regulatory professionals wherever they live and work. We have members from all over the world – in more than 50 countries. It is our ambition to double our international membership over the next three years.

TOPRA members reflect the global healthcare regulatory profession and share a common interest in European regulatory affairs and come together to discuss EU-wide regulatory issues. Many members also appreciate the opportunity to network with their peers in national TOPRA In groups to address local issues.

A GLOBAL PERSPECTIVE

TOPRA has always had an international focus, working with many partners to deliver conferences and courses from Singapore to Washington DC. TOPRA is now working with organisations committed to building regulatory capacity in emerging markets, particularly India and Africa.

TOPRA's first conference in India in 2017 focused on harmonisation, capability building and the latest trends; it attracted delegates from across the continent.

OUR COMMITMENT

GREATER ACCESS FOR ALL

Supporting regulatory professionals through membership is a priority for TOPRA. Although increases in numbers are important, greater engagement and participation are even more so – to enable members to support each other and help shape and improve the global healthcare environment.

TOPRA In groups are central to a dynamic member-led organisation. So too, are online communities and Special Interest Networks (SPINs), which enable sharing of information and expertise with peers in a safe professional environment.

TOPRA will also be expanding its programme of meetings and conferences across Europe, North America and Asia.

DIGITAL OUTREACH

TOPRA's online services can be accessed at any time. Investment in www.topra.org is ongoing to ensure visitors and members alike can quickly seek the information or service they require. The public pages cover the role of regulatory affairs and highlight its importance to a wider audience. Behind the public face is much, much more for members.

TOPRA uses technological advances to improve the online experience for members, such as developing mobile responsive websites.

CELEBRATING DIVERSITY

TOPRA is a signatory to the Science Council's Declaration on Diversity, Equality and Inclusion, which commits us to putting diversity at the heart of all we do. TOPRA's commitment to equality, diversity and inclusion is clearly visible and actively supported.

INFLUENCE

TOPRA gives a voice to the global healthcare regulatory profession, enabling legislators and opinion leaders to access the best possible information from among our diverse membership, which in turn strengthens healthcare regulation for everyone.

TOPRA provides a neutral platform for discussions across a wide range of disciplines that input into the regulatory environment. This enables opinion leaders, including regulators, to share the expertise of our members, and help shape the future of regulation so that it serves patients and consumers effectively.

Senior regulatory professionals and Fellows often want to give back to the profession. TOPRA offers opportunities to share expertise via working parties on a wider scale and the chance to interact at a one-to-one level with less experienced regulatory professionals through mentorship.

REGULATORY RAPPORTEUR

TOPRA's peer-reviewed journal, *Regulatory Rapporteur*, is well-respected and widely read by members and the profession in general. Its content provides up-to-date information and analysis of the key regulatory issues and developments, often contributed by regulators and key opinion leaders.

OUR COMMITMENT

DEVELOPING THOUGHT LEADERSHIP

Sharing of ideas with peers at high-level conferences, roundtables and networking events helps develop informed opinions and regulatory leaders for the future. TOPRA's conferences with regulatory partners such as the Heads of Medicines Agencies and European Commission, allow a two-way conversation between those developing new regulations and those who will be implementing them.

DRIVING REGULATORY SCIENCE

Regulatory scientists are at the heart of delivering accelerated approval initiatives, such as PRIME, working with sophisticated new technologies and scientific tools. TOPRA is committed to supporting those in leading edge roles by offering fora for high-level technical discussions, such as the Annual Summits and Horizons conferences and relevant CPD opportunities.

REPRESENTING THE PROFESSION

TOPRA gives voice to individual regulatory professionals contributing to regulatory consultations from a professional perspective rather than a company or commercial view.

TOPRA's participation into relevant industry and regulatory groups feeds into discussions on the impact of political decisions, such as the UK leaving the EU, on regulatory professionals both in the UK and Europe.

On an individual level, TOPRA commits to research to keep members in touch with issues related to their careers, salary levels and job prospects.

www.topra.org/2020

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