

ANNUAL REPORT 2017–2018



Celebrating **40 years** of promoting regulatory excellence

FROM THEN TO NOW

‘Life is divided into three terms – that which was, which is, and which will be. Let us learn from the past to profit by the present, and from the present, to live better in the future’

William Wordsworth



PRESIDENT'S MESSAGE

In 2018 TOPRA celebrates 40 years of supporting the regulatory profession as it has developed from an administrative function to one which is central to the delivery of safe and effective healthcare products.

I am proud to be your President at a time when we can look back on so many achievements. I salute our founding fathers for their vision, and for their courage in establishing a nascent professional body when the role of a 'registration officer' was barely given professional acknowledgment. I admire their forethought in setting up the 'Introductory Course' in regulatory affairs, which this year has also celebrated its 40th incarnation as the gold standard for training in our field: I was delighted to learn that the instigator of that first course, R Keith Greenwood, was able to address the students at the 40th event! Even those early innovators could never have foreseen the scope and breadth of today's TOPRA MSc programme.

In the last 40 years, the regulatory landscape had changed beyond recognition. At that time the EU system of regulation was in its infancy: the EMA was not established until 1995, and most products were the result of chemical synthesis, developed by a classical pathway and delivered by trusted physicians and pharmacists to their patients.

Today the range of products is complex and the healthcare system disrupted by technological innovation. Developments in medicine, science, legalisation, economics, populations and politics mean that modern day regulatory professionals must navigate an increasingly complex system and be ready to meet all the challenges it brings.

So how has TOPRA responded? In recent years we too have innovated, to evolve from a local membership association providing training and information, to a fully-fledged, international and respected professional body. We provide a structured training and development pathway, a range of qualifications, a robust competency framework and an independent, internationally-recognised personal accreditation system (CSci), giving regulatory practitioners the tools to be the best they can be in the, as yet uncertain, future. We continue to provide support to individuals wherever they work and to link colleagues together across the globe.

TOPRA has never lost sight of the fact that it exists to promote the profession and to support its members. In the last 40 years, successive Boards have steered the organisation through times of change and will continue to do so as the EU regulatory system and its global relationships enter a new phase.

Thank you for your support.

Angela Stokes | President 2018

TOPRA Board members 2018

President	Angela Stokes
Past President	Bob Clay
President Elect.....	Nick Sykes
Director with focus on EU.....	Sue Harris
Director with focus on North America	Natalie Tolli
Director.....	Aileen Fisher
Director.....	Ann Nallen
Director.....	Elizabeth Madichie
Director.....	Sharon Gorman



‘Whatever life throws at us, our individual responses will be all the stronger for working together and sharing the load’

Elizabeth II

TOPRA Staff members 2018

Executive Director	Lynda J Wight*
Director of Operations.....	Kevin Pay
Director of Publications	Jenine Willis*
	and Communications
Director of Policy (to Sept 2018)	Tacye Connelly*
Head of Professional Development.....	Samantha Alsbury
Head of Membership and Data Insight...	Sinéad Whelan
Financial Controller	Vincent Costello
Client Liaison and Sales Manager.....	Erik Smit
Managing Editor	Madeleine Meyer*
Regulatory Intelligence.....	Christopher Bailey*
	and Conferences Manager
Regulatory Training.....	Andrew Thornley*
	Manager (to Oct 2018)
Accounts Assistant.....	Jatinder Gill
Communications Editor	Benedict Lam
Digital Editor	Cliff Annicelli
Membership Officer (to Sept 2018)	Karolina Nowak
Office Services.....	Valentina de Marinis Perez/ Paul Rosenthal
Postgraduate Administrator.....	Kay Platt
Training and Conference.....	Sarah Roberts
	Logistics Manager
Training and Development Officer	Sammi Kwok

* Part-time personnel

TOPRA Advisory Council Members 2018

Alan Morrison (UK)	John Wilkinson (UK)
Pat O’Mahony (Ireland)	Ann O’Connor (Ireland)
Larry Liberti (USA)	Peter Bachmann (Germany)
Daniel Basseur (Belgium)	Martina Struck (USA)
Robert Johnstone (UK)	Daniela Drago (USA)
Mel Walker (UK)	Rob Kowalski (USA)
Greg Perry (Switzerland)	Murray Lumpkin (USA)
Rui Santos Ivo (Portugal)	Tomas Salmonson (Sweden)

EXECUTIVE DIRECTOR'S MESSAGE

It is fitting that we celebrate TOPRA's 40 years of support for the regulatory profession.

As I have looked through our archive it has become clear that apparently small developments have accumulated over the decades into significant achievements, not just for TOPRA as an organisation but for all of us in the regulatory profession.

During my own long association with TOPRA, from new recruit on the first Introductory Course, to keen volunteer, to Board member and finally employee, I can see clearly how being involved with TOPRA has supported me and those around me in our professional lives. I remain as convinced today of the value of this community – committed to providing the means for continuous personal improvement and the promotion of our profession – as I was when I first joined.

The past two years have seen several initiatives come to fruition, including:

- our careers fairs and increased support for students and those entering the profession
- the acceptance of our competency framework as a benchmark for the profession
- the approval of our postgraduate-level apprenticeship standard
- our expanded post-graduate qualifications programme – now also giving device specialists a range of dedicated qualifications
- our first accreditations of individual regulatory practitioners as Chartered Scientists (CSci)
- our accredited training programmes for agencies and industry partners
- our increased activity on the global stage.

However, alongside our mood of celebration we are also faced with challenges. This means we need to continually innovate and evolve with the changing environment, using the responsiveness to change that we have demonstrated in the past. We must *'learn from the past to profit in the present and in turn, do better in the future'*.

TOPRA has traditionally been placed at the heart of EU regulation. As that centre of gravity changes in the next 12 months, our new additional office in Brussels will ensure that we continue to be so. TOPRA members who achieve CSci will have a 'passport' to opportunities in the profession, wherever they choose to work. And while TOPRA has always been valued for the quality of its training and relevance of its conferences, it will be its role as THE professional body, setting standards and promoting professional competence across the world, which will be to the fore in the future.

I would like to pay tribute to the TOPRA staff team and all the tremendous volunteers in our membership who have, since the day TOPRA was conceived, helped us to achieve so much – and with them we will continue to have an even better future.

Lynda J Wight | Executive Director

LEARNING FROM THE PAST

‘Study the past, if you would divine the future’ Confucius

Nine subscribers who signed our constitution in November 1978 committed the organisation to fulfilling the following objects:

- ✦ To establish a professional **identity** and **standards** for regulatory affairs personnel in the pharmaceutical and related fields
- ✦ To promote **education** and **science** in regulatory affairs
- ✦ To advance the **professional competency** of its members
- ✦ To promote **co-operative relations** with other allied organisations
- ✦ To collect and circulate relevant **statistics** and **information** of all kinds.

These were ambitious goals at a time when ‘product registration’ was poorly understood, geographically fragmented and under-valued; being regarded as a potential barrier to commercial success, rather than an enabler of innovation.

In the following years, these goals have been accomplished, yet remain valid for TOPRA today where education, co-operation, standard-setting and competence remain at the heart of our strategy. Since 1978, successive leadership teams have developed the tools to promote the professional identity of those working in healthcare regulation, culminating in TOPRA being licensed by the Science Council to award the Chartered Scientist accreditation (CSci) in 2018.

One lesson runs like a golden thread through the endeavours of the last 40 years: that the contributions of the volunteers in the membership are critical to our success. From the founders of the MSc programme to the editors of *Regulatory Rapporteur*, from those who run member networks to programme committee members, all have been integral to TOPRA’s success in establishing a distinct and competent profession.



‘Volunteering with TOPRA is a great opportunity to give that little bit back by supporting TOPRA’s initiatives and events, engaging with other members and building your professional network. I want to make more people aware of regulatory affairs as a career option and volunteering with TOPRA allows me to do this in a flexible, interesting and rewarding environment!’

Ashley Dukes

Chair of the Young Professionals Special Interest Group and lecturer at ‘TOPRA Careers Live!’

RESPONDING TO CHANGE

– how TOPRA’s past has established its present role

Year	
1978	Company established ; first ‘member newsletter’
1979	First Symposium, University of Nottingham, UK
1980	First Introductory Course, London, UK
1982	First journal
1986	Establishment of a European entity
1989	Postgraduate qualification established
1992	First Postgraduate Diplomas awarded
1995	Heron Quays offices opened by Rolf Bass (BfArM)
1996	First PEFRAS (Pan European Federation of Regulatory Affairs Societies) Congress
1997	First MSc awarded
2003	BIRA Silver Jubilee celebrations ; joint BIRA and ESRA conference, Brussels, Belgium
2003	New constitution to establish the TOPRA name and brand
2004	TOPRA Launched in London and Brussels with Daniel Brasseur (CPMP) and Phillipe Brunet (EU Commission)
2004	First edition of <i>Regulatory Rapporteur</i>
2004	First joint conference with the EU Commission, Brussels, Belgium
2005	First joint meeting with EMA, Brussels, Belgium
2006	First conference in North America, Washington DC, USA
2006	First Annual Symposium in partnership with a national agency (MEB), Amsterdam, The Netherlands
2010	First Awards for Regulatory Excellence
2014	First on-line course
2014	First training events in Hong Kong and Singapore
2015	Move to current offices at Harbour Exchange
2016	First TOPRA Summit
2017	First conference in Bangalore, India
2017	Refreshed constitution agreed at EGM
2017	Competency framework launched
2017	First conference with HMA, Tallinn, Estonia
2018	Apprenticeship standard approved
2018	Re-validated 22-Module medicines and medical devices MSc launched
2018	First CSci awarded

PROFITING FROM THE PRESENT

‘What makes a professional is not merely an academic excellence; it is in the possession of the relevant virtues related to the professional’s area of expertise’

Michael Quansah, Life Coach, Ghana

In the past year TOPRA and its members have achieved outstanding results both for themselves and for the organisation.

Establishing standards for the profession

Following the publication of the TOPRA *Competency Framework*, employers are now using this as a basis for their staff development programmes, either independently or in conjunction with TOPRA.

The TOPRA *Salary Survey* gave the regulatory community an insight into the present situation and expectations of future changes.

TOPRA has worked with employers, both in the industry and agency sectors, to deliver bespoke training solutions, some as ‘one-off’ learning opportunities and others as accredited training programmes for teams. Vijayalekshmi Dharmajan was the first ‘graduate’ of a jointly accredited training programme for the devices section at MHRA, with more due to follow by the end of 2018.

Following months of work by a cross-sectional employer working group, led by TOPRA, the first Regulatory Affairs Specialist apprenticeship standard was approved in 2018, and TOPRA was also approved as an accredited training provider. This standard will provide a benchmark for employers in training new entrants to the profession.



LEARNING AND NETWORKING

in an international community

In Spring 2018 TOPRA partnered with the Maltese Medicines Authority to present open training courses for regulatory professionals and to support the agency's in-house professional development objectives.



TOPRA has signed a Memorandum of Understanding with the Centre for Regulatory Excellence (CoRE) in Singapore to explore collaboration opportunities.



Students from the University of Southern California visited TOPRA In April 2018.



Danish Life Science organisation Synapse Connect brought students to TOPRA in June for a seminar on careers in regulatory science.

TOPRA was invited to the Association of Graduate Regulatory Educators in the US and Samantha Alsbury was elected to the Board.

Thought-leading conferences

Largest Annual Symposium in London

Over 650 individuals attended the multi-track event in October 2017, held in partnership with the Medicines and Healthcare products Regulatory Agency (MHRA).

Joint meeting with the Heads of Medicines Agencies

In December 2017, TOPRA held its first joint event with the HMA in Tallinn, Estonia.

3rd TOPRA Summit

Delegates discussed the implications of disruptive technologies on regulatory processes and competency requirements, producing a white paper with a series of recommendations and future action plans.



The TOPRA Annual Lecture 2017 was delivered by Dr Mac Lumpkin of the Bill and Melinda Gates Foundation

HMA meeting Tallin

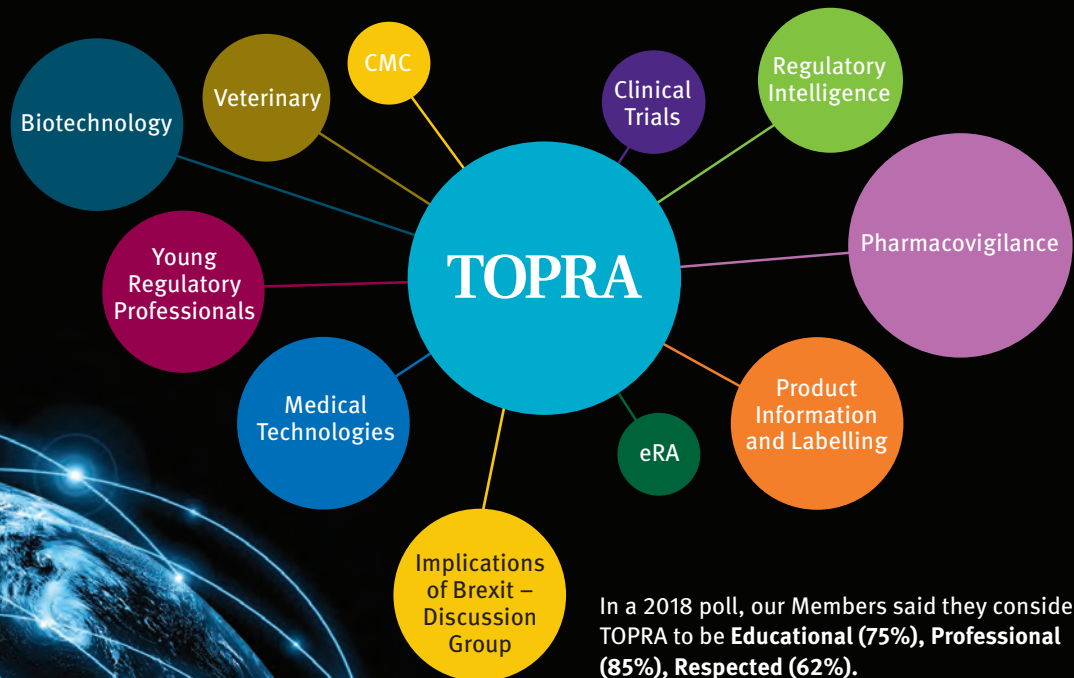
GLOBAL NETWORKING OPPORTUNITIES

TOPRA has members in over 50 countries.

New countries added to the TOPRA member community in 2017–2018 included Argentina, China, Finland, Qatar, the Russian Federation, Saudi Arabia and Ukraine.

The top ten countries for membership are Belgium, France, Germany, Ireland, Netherlands, Spain, Sweden, Switzerland, United Kingdom and the United States of America.

In 2018 TOPRA introduced a programme of on-demand webinar resources covering global regulatory affairs covering regions including Asia, South America, Middle East and Africa.



In a 2018 poll, our Members said they consider TOPRA to be **Educational (75%), Professional (85%), Respected (62%)**.

Regional, member-managed TOPRA In groups continue to provide members with opportunities to network at a local level in locations from France to Sweden, USA to Scotland.

Subject-specific networks bring members together for webinars and access to support and resources. In 2018 the 'Brexit' SPIN was especially popular!

PROFITING FROM THE PRESENT

‘We don’t get a chance to do that many things, and every one should be really excellent’ Steve Jobs

TOPRA gives its members opportunities to be recognised and rewarded for their individual contributions to our profession.

Achieving Chartered Scientist accreditation

TOPRA was licensed to award CSci, which is recognised in EU professional mobility legislation, in 2017. The first CSci awards were conferred in 2018 to: Antonia Orsi, Lorna Griffin, Mojisola Ajeneye



‘The application journey has allowed me to reflect on my work-based, self-learning and continuing professional development activities over the years, and how valuable they were. I would encourage fellow colleagues... to consider aiming for this prestigious status.’

Mojisola Ajeneye
UK Medicines and Healthcare products
Regulatory Agency

Mastering regulatory affairs

The latest graduates from the TOPRA postgraduate educational programmes with University of Wales and the University of Hertfordshire are:

MSc with Distinction: **Susanne Darnieder; Noreen Duggan; Sonja Jakobs**
MSc with Commendation: **Clare Horner**
MSc: **Jasmina Savic**
Postgraduate Diploma with Distinction: **Antonia Fleming; Juliet McGillycuddy**
The Veronica Skeffington Prize for best student was awarded to: **Noreen Duggan**

Acknowledging thought-leaders

Nominated by their peers and endorsed by the Board after a rigorous review process, the following were accepted into Fellowship of TOPRA in 2017–2018:

Sylvia Lobo, David Gilbert, Rob Higgins, Paula Buffery, Thomas Kühler, Lesley Reeve, Catriona Cutting, Rose-Marie Swallow, Mehryar Behizad, Anja Holm, Paul Marshall, Sally John, Mark Hope, Pierre-Frederic Omnes, Usfeya Ahmad Muazzam, Paul Browning, Melanie Munro, Daniela Drago, Majella Ryan

Recognising contribution

In the last year the following were admitted as Honorary Members of TOPRA:

John Deavin (Fellow), Patrick Salmon, John Wilkinson

CELEBRATING EXCELLENCE



The winners of the 2017 Awards for Regulatory Excellence were:

Communication:	Julie Holtzople and the Clinical Trial Transparency Team – AstraZeneca, USA
Contribution:	Clare Ryder – PPD, UK
Futures:	Michela Gabaldo – San Raffaele-Telethon Institute for Gene Therapy, Fondazione Telethon, Italy
Innovation:	John Wilkinson – Dr John Wilkinson Natural Product Consultancy, UK
Education:	Orin Chisholm – UNSW Sydney, Australia
Horizon:	Oliver Rick – TRAC, UK
Inspiration:	Abbie Lennox – RB, UK
Support:	PPD/Evolus Global Marketing Authorisation Project team – PPD
Lifetime Achievement:	Sue Forda and Melanie Leivers

Recognising exceptional services to TOPRA

Distinguished Service Awards

Individual volunteers recognised for their contribution to TOPRA activities are Lisa Pascoe for her role in managing the CMC SPIN group and Chris Walker for his input into the Annual Summit.

Top Team

The TOPRA Apprenticeship Panel was recognised as the 2018 Top Team of volunteers.

LIVE BETTER IN THE FUTURE

‘The power for creating a better future is contained in the present moment: You create a good future by creating a good present’ Eckhart Tolle

Responding to change

From November 2018 TOPRA has additional office facilities in Brussels which will allow us to continue to interact with key EU stakeholders and also offer space to members, committees and for training. Our UK headquarters will continue to be the focus of co-ordination of our global activities.

Partnerships for success

In November 2018 TOPRA will collaborate with the US-based Regulatory Affairs Professional Society (RAPS) on a multi-stakeholder event on drug-device combination products.

TOPRA will continue its global activities with partner organisations in Asia, India, North and South America to add value and promote excellence. This included TOPRA presence at the ICDRA (International Conference of Drug Regulatory Agencies) pre-conference in Dublin in September 2018.

Working with industry and agency partners TOPRA will continue its development of bespoke accredited training programmes.

In 2019 the TOPRA Annual Symposium will be held in partnership with the Healthcare Products Regulatory Agency (HPRA) in Ireland.

Celebrating **40 years** of promoting regulatory excellence



REACHING OUT – DIGITAL & DIVERSITY

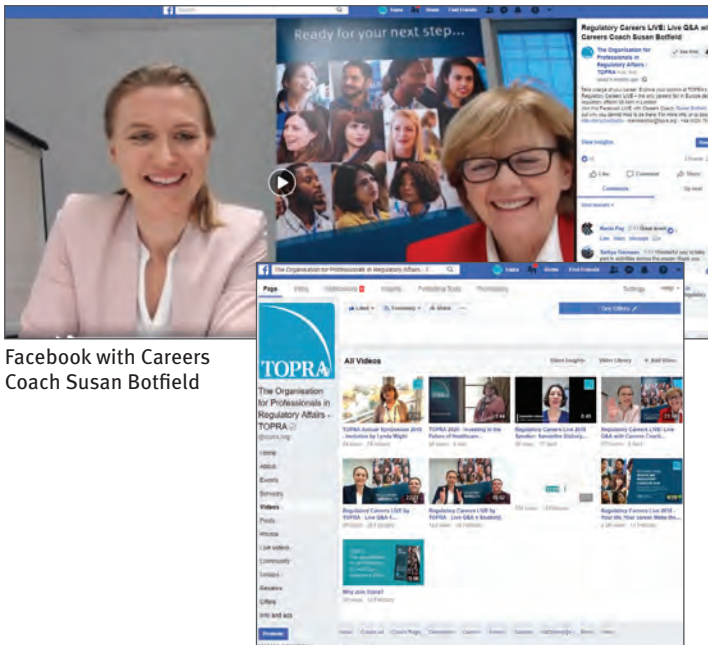
‘Diversity and inclusion, which are the real grounds for creativity, must remain at the centre of what we do’ Marco Bizzarri, CEO, Gucci

TOPRA has increased its use of technology to improve the delegate experience at the Annual Symposium, and has piloted the use of digital voting at key events.

Deepening our digital footprint

During 2017–2018 TOPRA has deepened its engagement with stakeholders through social media channels. Coordinated communications campaigns across multiple platforms have delivered TOPRA news to members and potential members across the globe.

In 2018–2019 the TOPRA website will be re-shaped to deliver additional digital services and an improved digital experience for users.



Facebook with Careers Coach Susan Botfield



TOPRA staff enjoying celebrating Diversity Day

Encouraging diversity

TOPRA remains committed to a structured diversity agenda to ensure the regulatory profession, and in particular TOPRA's activities, are accessible and welcoming to all. TOPRA staff celebrated their own inclusivity with a lunch on International Diversity Day!

FINANCES – PAST, PRESENT AND FUTURE

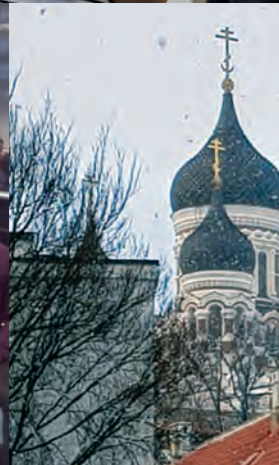
Over the past 40 years, careful stewardship and management of reserves have given the organisation a secure underpinning. The value of the reserves as at 31 December 2017 was £2,002,291. This is line with the reserves policy and industry benchmarks.

As a non-profit organisation, the present-day activities of TOPRA are geared towards meeting the needs of members and not simply by commercial imperatives. Turnover for the year increased and direct costs were held, but administrative expenses increased leading to an operating deficit of around 3% of turnover. Strong performance from the investment portfolio lead to an overall surplus after tax of over 4%.

Statement of profit and loss for year ending

	December 2017	December 2016
TURNOVER	2,027,759	1,961,022
Cost of sales	1,223,703	1,228,648
GROSS SURPLUS	804,056	732,374
Administrative expenses	864,288	766,119
Other operating income	(955)	756
OPERATING DEFICIT	(61,187)	(32,989)
Income from fixed asset investments Including interest receivable and similar income	44,194	40,775
Gain/loss on revaluation of investments	126,795	177,096
SURPLUS/(DEFICIT) before taxation	109,802	184,882
Tax	21,001	23,363
SURPLUS/ (DEFICIT) FOR THE FINANCIAL YEAR	88,801	161,519

In the future, new initiatives will use the accumulated funds to continue to deliver a professional association working on a global stage in an increasingly digital environment, to support members and encourage excellence.



www.topra.org

The Organisation for Professionals in Regulatory Affairs Ltd
6th Floor, 3 Harbour Exchange, South Quay, London E14 9GE
Tel: +44 (0)20 7510 2560 Fax: +44 (0)20 7537 2003
Email: topra@topra.org Web: www.topra.org

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