

MY TOPRA

Be the best you can be with
your TOPRA membership

The professional membership organisation for regulatory
affairs professionals across the globe.



Be the best you can be with TOPRA

Our mission is to represent and promote the profession of healthcare regulatory affairs globally. To do this we will provide exceptional support, world-class education and definitive accreditation for all regulatory professionals, and celebrate excellence in regulatory practice.

Find out more at www.topra.org/membership

There are many reasons why regulatory professionals join TOPRA

Belong

to a vibrant global
regulatory community

Engage

share and learn from
your peers

Develop

your professional
competence

Advance

your career

Contribute

to the development
and recognition of the
profession globally

Access

authoritative
information and
high-quality learning
opportunities

Refresh

your knowledge on
the latest regulatory
developments

Benefit

from preferential
member rates

Our ethos

TOPRA is a member-driven organisation. Our members are individuals working in regulatory affairs all over the world. They come from a range of healthcare sectors, including regulatory bodies, academia, regulatory affairs consultancies, the pharmaceutical, veterinary and health technology industries, clinical research organisations and many others.

Among the many reasons that regulatory professionals join TOPRA is that it signals to colleagues and employers a strong commitment to the regulatory profession. You become part of a diverse global community of regulatory professionals with defined values and standards of good practice.

We provide our members with top-quality, relevant support with a European focus. We support you throughout your career to help you perform to the highest level and to help retain the brightest and the best within the profession.

'TOPRA is the leading regulatory professional association that offers the best opportunities for networking and professional development'



MY MEMBERSHIP

Categories explained

Our Membership categories cater for individuals at all stages of their career in regulatory affairs. Are you in the most appropriate category?

Student Member

For those in full-time education or within one year of graduation. Do you know a science student interested in RA? Recommend this category to them.

Member

This is the most popular category of Membership, which allows any individual with an interest in regulatory affairs to become a Member of TOPRA. This category usually encompasses people with fewer than 2 years' experience or individuals supporting regulatory affairs projects/departments.

Have you got more than 2 years' RA experience? Upgrade to Registered Member and get your

MTOPRA designation now with our MTOPRA wizard: www.topra.org/mtopra

Registered Member

Only Members with more than 2 years' experience who have committed to ongoing professional development are eligible to use MTOPRA designation.

Are you a Registered Member? Add MTOPRA to your email signature and social media channels to signify your commitment to the profession.

Fellow

TOPRA Members with at least 10 years' experience in regulatory

affairs who have made a significant contribution to the profession can be nominated by their peers or self-nominated to become Fellows. With many Members applying or being nominated for Fellowship, we are proud to have such a high level of distinguished professionals among our membership. Read some Fellows' case studies online: www.topra.org/fellow

Honorary Member or Honorary Fellow

At its discretion, the Board of TOPRA can appoint individuals who have been important in the field of regulatory affairs as Honorary Members or Honorary Fellows.

Student

For those in full-time education or within one year of graduation. Do you know a science student interested in RA? Recommend this category to them.

Member

This is the most popular category of Membership, which allows any individual with an interest in regulatory affairs to become a Member of TOPRA.

MTOPRA

Members with more than 2 years' experience who commit to CPD are eligible to apply for **Registered Member** status and use MTOPRA designation.

FTOPRA

Fellowship is available to TOPRA Members with more than 10 year's experience who have made an impact on the profession.

Honorary

The TOPRA Board can recognise individuals who have been important in the field of regulatory affairs as **Honorary Members** or **Honorary Fellows**.

MY TOPRA

Benefits at a glance

Member Benefit	Student Member	Member	Registered Member (MOPRA)	Fellow	Honorary Member/ Fellow
Information services					
<i>Regulatory Rapporteur</i> – monthly journal		✓	✓	✓	✓
<i>Regulatory Rapporteur</i> Online (with digital archive)	✓	✓	✓	✓	✓
Quarterly CPD supplements with <i>Regulatory Rapporteur</i>	✓	✓	✓	✓	✓
<i>InTouch</i> monthly Member newsletter	✓	✓	✓	✓	✓
<i>Vet Med Update</i> – monthly newsletter	✓	✓	✓	✓	✓
<i>MedDev Update</i> – monthly newsletter	✓	✓	✓	✓	✓
<i>Life-Lines</i> – fortnightly newsletter on Brexit & legal matters	✓	✓	✓	✓	✓
Daily news feed on the latest developments in pharmaceuticals (<i>Pharma Times</i>)		✓	✓	✓	✓
Discount for MedBoard, an integrated medical device information platform		✓	✓	✓	✓
Member engagement					
SPINs – networks for members with shared professional interests	✓	✓	✓	✓	✓
TOPRA In groups – country or regional groups for networking and discussions	✓	✓	✓	✓	✓
Free SPIN/TOPRA In events & webinars		✓	✓	✓	✓
Consultations from key stakeholders in RA		✓	✓	✓	
Volunteering opportunities	✓	✓	✓	✓	✓
Governance – standing for or voting in Board Elections		✓	✓	✓	
Career support					
Member discounts on courses and webinars	✓	✓	✓	✓	✓
CPD recording tool		✓	✓	✓	
Careers Fair complimentary pass	✓	✓	✓		
Careers advice – ½ hour telephone or video conference session		✓	✓	✓	
Free RA Careers webinar	✓	✓	✓	✓	
Post-nominals: MOPRA			✓		✓
Post-nominals: FOPRA				✓	✓
Apply for personal accreditation: Chartered Scientist (CSci)			✓	✓	
Apprenticeship training	✓	✓			
Commercial services					
Discounted meeting rooms at TOPRA HQ London		✓	✓	✓	✓
10% discount on online recruitment advertising		✓	✓	✓	✓

MY TOPRA

My Professional Body

Governance – Board

The Board of Directors is the legally and financially responsible body that sets the strategic direction of TOPRA and makes sure that all is running smoothly. There are Board Elections every year, which all Members apart from Students, Honorary Members and Honorary Fellows may vote in. Any voting Member of more than one year, wherever they live or whatever their regulatory experience, can stand for election. www.topra.org/board

Expert Advice – Advisory Council

All Members of TOPRA can make recommendations to the Board, in confidence, for new Advisory Council members. The Council meets twice a year and provides a valuable external perspective on regulatory affairs and the needs of the regulatory profession.

Annual Review

All TOPRA Annual Reports are available to view online and every voting Member is welcome to join the Annual Review meeting (usually at the Annual Symposium). See previous reports: www.topra.org/annual-reports

Consultations

TOPRA aims to keep members informed of important consultations as they are

issued. Consultations are sent to relevant working parties/SPINs and posted online: www.topra.org/consultations

Celebrating Diversity

TOPRA is a signatory to the Science Council's Diversity Declaration. This commits us to putting diversity at the heart of all we do as an organisation, and to consider the importance of diversity for the regulatory affairs profession.

Priorities for 2019 and beyond:

- Actively promoting regulatory affairs as a profession that welcomes people from diverse backgrounds
- Ensuring that our commitment to equality, diversity and inclusion is clearly visible and actively supported
- Ensuring we collect information on equality, diversity and inclusion issues that relate to our membership for the purposes of our role as a member organisation and to our staff for the purposes of our employment role.

A Board-appointed Member is nominated to run the Diversity Working Party, which comprises TOPRA members and staff.

Find out more at www.topra.org/diversity for updates, case studies and more.



'I remain as convinced today of the value of the TOPRA community – committed to providing the means for continuous personal improvement and the promotion of our profession – as I was when I first joined 40 years ago'

Lynda Wight
Executive Director,
TOPRA



Volunteering

TOPRA is your professional membership organisation – with a proud history of being led *by* regulatory professionals *for* regulatory professionals. There are many ways you can participate and contribute.

Ways to volunteer with TOPRA as a Member:

- Symposium volunteering (for Student Members)
- Course working parties
- TOPRA committees (eg, Diversity)
- Special Interest Network steering groups (SPINs)
- Territory-based network steering groups (TOPRA In groups)
- *Regulatory Rapporteur* Editorial Board
- Speaker/Presenter at meetings
- *InTouch* editorial opportunities

Visit www.topra.org/volunteering

Recognition

TOPRA appreciates all the help and input of its volunteers. We support our volunteers so they can get on with the activities they enjoy, that they find most interesting and satisfying. The efforts of our volunteers are always acknowledged and we like to say thank you!

TOPRA has two main awards to recognise volunteers:

- **Distinguished Service Award**
- **Top Team Award.**

Visit www.topra.org/recognition

‘Being a TOPRA member gives you a sense of belonging and a platform to share, learn, get inspired and make a difference’

MY COMMUNITIES

Networking/engagement

The TOPRA In groups and Special Interest Networks (SPINs) organise and contribute to TOPRA's overall aim to support the regulatory profession. They run local events; arrange online webinars; source/contribute country specific articles in *Regulatory Rapporteur*; input into course development; get involved with our Annual Symposia, careers fairs and much more.

You can join as many online communities as you like in the MY TOPRA section of the website. If you want to be part of a SPIN or TOPRA In steering group, email membership@topra.org

TOPRA Special Interest Networks (SPINs)

- Promote contact between regulatory professionals working in the same specialist sector
- Provide a forum for exchanging views and ideas and for mutual support
- Ensure that the needs of these sectors are taken into account in the TOPRA training programme and encourage expert input into the content of courses
- Encourage contributions to *Regulatory Rapporteur* on specialist topics.

TOPRA In...

TOPRA In groups support regulatory professionals living and working in a country or region, providing a forum for discussion and networking.

The groups aim to:

- Develop a local TOPRA networking arm in individual countries for meetings and discussion
- Support the TOPRA members living and working in a country and increase membership among regulatory professionals
- Work cooperatively with other government or not-for-profit organisations and relevant academic institutions.

For everyone

We have two online communities that attract interest across the entire membership. These are:

- TOPRA Members' Community – which is an opportunity for members to share their news and raise discussions with all members who have signed up to this group
- Implications of Brexit discussion group – an active forum that attracts a lot of interest.



SPINs	TOPRA Ins
Biotechnology	Austria
CMC	England and Wales
Regulatory Operations	France
Medical Technologies	Ireland
Regulatory Intelligence	Italy
Clinical Trials	North America
Pharmacovigilance	Scotland
Veterinary	Sweden
New Regulatory Professionals	Switzerland
Product Information and Labelling	Spain
	The Netherlands

‘Membership to TOPRA shows I am actively engaged with the regulatory affairs profession, with my finger on the pulse’

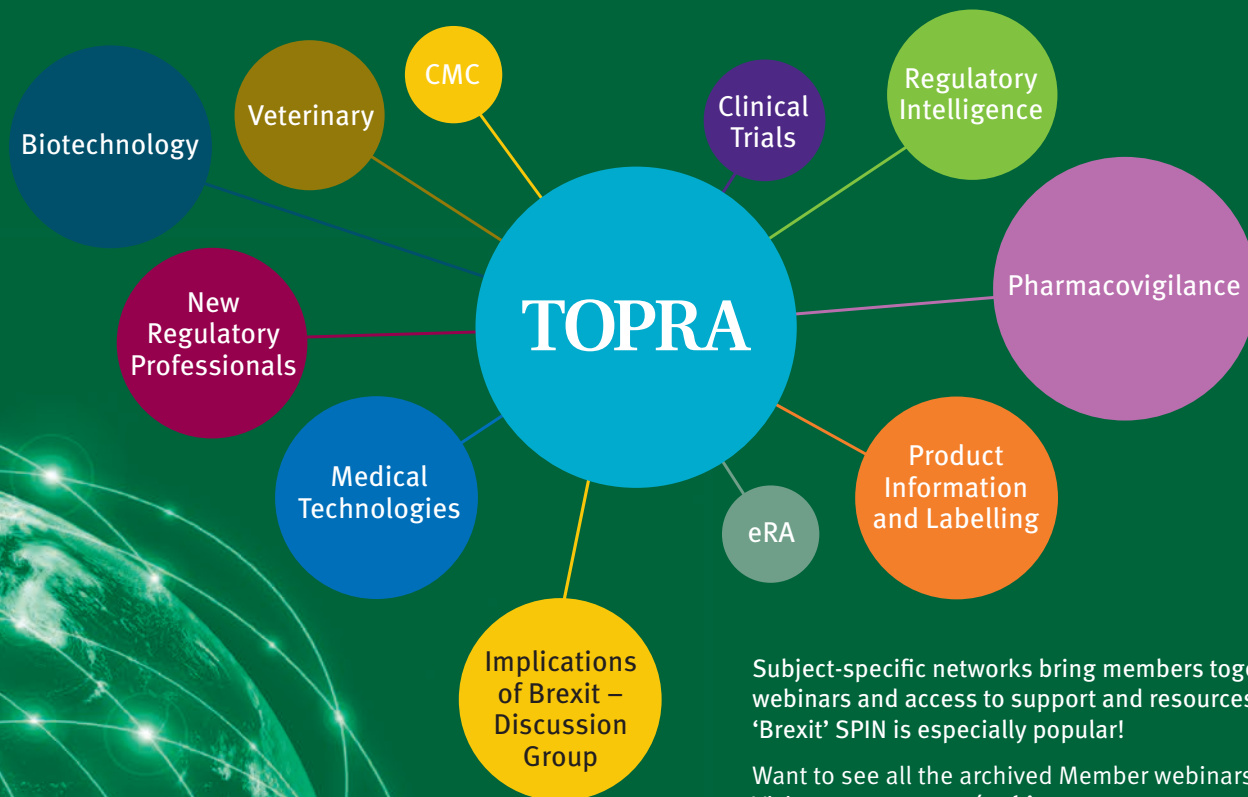
Global Networking Opportunities

TOPRA has members in over 50 countries.

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

Countries recently added to the TOPRA member community include Argentina, China, Finland, Qatar, the Russian Federation, Saudi Arabia and Ukraine.

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



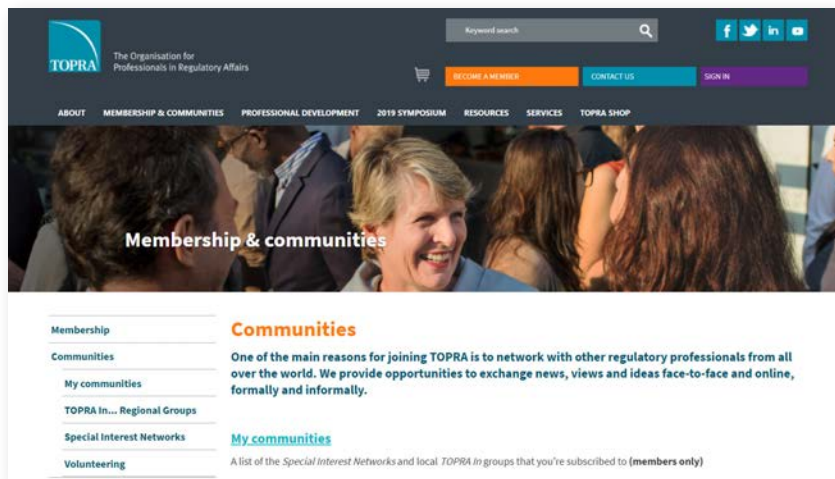
Subject-specific networks bring members together for webinars and access to support and resources. The 'Brexit' SPIN is especially popular!

Want to see all the archived Member webinars? Visit www.topra.org/webinars



Our SPINs and TOPRA In groups provide a variety of resources such as free Member webinars, presentations, articles and Q&As, while some also host face-to-face meetings.

Once you sign in at www.topra.org/signin, go to **MEMBERSHIP & COMMUNITIES > Communities** to access the online networks you have joined:



Why our members think it is important to be part of TOPRA:

‘Belonging to a global professional organisation’

‘Professional high-level support and engagement’

Top Tip

Ensure you add contact@topra.org to your list of contacts so you receive automated alerts whenever a new discussion or announcement is posted.

MY TOPRA

My Professional Body

Over

20

member network events
and webinars each year

Over

60

volunteers leading
these networks

11

Territory based networks
covering Europe and
North America

Up to

25%

of our members are participating
and engaging in the TOPRA In
online communities

PARTNERSHIPS

Benefiting members

NEW! Employer Champions

Would your organisation benefit from the ability to pay for TOPRA membership subscriptions as part of a bulk invoice (minimum number 50 Members)? This does not affect your individual membership, only the way it is processed. You have your own account with access to all Member benefits, including discounts on courses. Because the payment system is simpler and more cost-effective it may also mean that more of your colleagues can benefit from TOPRA membership.

Advantages to Employers

- **Champion status** – each organisation signing up for this annual package is listed on our Employer Champions' page on www.topra.org/employerchampion to signify its commitment to regulatory professionals in its company
- **Easy to administer** – removes the obstacle of each employee claiming back the cost of TOPRA subscription
- **Cheaper** – with one invoice, the overall cost of membership is reduced by signing up to this package
- **Encourages professional development** – provides a professional membership to more of your employees giving them access to accreditation and member-only information
- **Promotes regulatory excellence** – offers the ability to benchmark staff against a common standard based on the TOPRA Competency Framework
- **Access to CSci accreditation** – TOPRA is approved by the Science Council as an awarding body for Chartered Scientist.

Check whether your company is an Employer Champion by emailing membership@topra.org



Employer Champion

Supporting Regulatory Professionals



'TOPRA is an excellent organisation that provides current information to its members and offers training courses that meet the customer's needs'

PARTNERSHIPS

Supporting Members' interests

TOPRA works with a wide range of organisations – from regulatory agencies to industry, from other membership associations to consultancies – across the world in every healthcare regulatory specialty.

Examples of recent partnerships include:

- the Swedish MPA on the TOPRA Annual Symposium in Stockholm
- the US-based Regulatory Affairs Professional Society (RAPS) to deliver a multi-stakeholder event on drug-device combination products in Brussels
- work with organisations like Perrigo and the MHRA to offer accredited training.

NEW! TOPRA is now collaborating with MedBoard, a single integrated medical device information platform, to produce *MedDev Update* every month for members. Additionally, members and their organisations will be eligible for a discount on a subscription to MedBoard's service.

Our partners include...

Partner for 2019 TOPRA
Annual Symposium



Partner for VetMed
Update newsletter



Partner for Life-Lines
newsletter



Partner for MedDev
Update newsletter



Partner for TOPRA MSc RA
(Medicines/Medical Devices)



Partner for Chartered
Scientist recognition



MY CAREER PATHWAY

Support at every stage

We are committed to supporting a culture of continuing professional development (CPD). Every regulatory professional needs to keep their skills and knowledge up to date, especially in a rapidly changing medical and regulatory environment.

How can TOPRA membership help your career?

TOPRA has a long-standing reputation as a training provider on healthcare regulatory affairs. Whether it is online, face-to-face, or blended learning, TOPRA can provide you with a programme of training courses and conferences on a range of regulatory affairs topics, at all stages of your regulatory career. See: www.topra.org/careers and www.topra.org/events

Careers coaching

Are you struggling to progress in your career? Are you interested in changing career? Are you looking for support to develop your team?

TOPRA can help – we can offer you some professional support via a session with Imaginarium Learning & Development to provide an objective review of your CV and interviewing skills and work together to build your career plan.



Top Tip

Why not use your free 30-minute telephone or video conference consultation with our Careers Consultant: www.topra.org/careerscoaching

Explore

For those wanting to take their first step into regulatory affairs or those in related disciplines who are considering a change of career direction or who need an overview

Establish

For those who have recently joined the regulatory profession or those whose regulatory experience is outside the EU

Consolidate

For experienced professionals committed to developing their regulatory knowledge, expertise and management competencies

Drive

For senior-level regulatory professionals taking on additional/strategic responsibilities or those looking to diversify their skills

Influence

For regulatory leaders and opinion-formers engaging in discussion, debate and networking opportunities across the regulatory profession and at a global level

MY CAREER PATHWAY

Building regulatory competencies

Competency Framework

TOPRA has developed a Regulatory Affairs Competency Framework, which is now being used as a benchmark by many organisations and as part of the Regulatory Affairs Specialist apprenticeship standard.

It is important that regulatory professionals have the necessary skills to keep up-to-date and add value to their organisation. This framework is an important contribution towards this goal. If you or your team want to develop core competencies to succeed in your field, contact our Head of Professional Development, Samantha Alsbury: samantha@topra.org.

CPD Recording Tool

All Members taking TOPRA courses will have their personal online CPD (continuing professional development) record automatically updated. You can also upload your other CPD evidence onto the recording tool (under My TOPRA).

Other CPD activities include reading, in-company training and volunteering. Over time you will build up an independent personal record of achievement and competencies covering a lifetime's career – offering a valuable addition to your CV.

www.topra.org/cpd



MY CAREER PATHWAY

Achieve professional accreditation

CSci
Chartered
Scientist

Since January 2018, TOPRA members can be evaluated for CSci status. This is a way for you to gain formal recognition of the competencies, experience and expertise you have developed and demonstrated over your career.

This professional registration recognises a high level of skill and experience independent of your scientific discipline. It is based on 15 broad scientific competencies and you need to show how you meet all of them in your daily work.

The Chartered Scientist Register is held by the Science Council, meaning that it is available to other scientists in the drug and device development process, thus providing parity for regulatory professionals with scientists working in research and development.

Chartered Scientist is also accepted for the purposes of directive 2005/36/EC as a regulated profession with the Science Council appointed as the Competent Authority. It is thus recognised across Europe.

TOPRA members who wish to apply for CSci designation must complete an application form to demonstrate, using their existing continuing professional development (CPD) evidence, how they meet the competency requirements. You can draw on the evidence you have included on your TOPRA online CPD Recording Tool.

NEW! Registered Scientist accreditation for less experienced regulatory professionals coming soon.



'The application for CSci has allowed me to reflect on my work-based, self-learning and continuing professional development activities over the years, and how valuable they were'

MY RESOURCES

Professional and collegial

As a global membership body, many of our membership benefits are available online. Find out about our monthly technical journal, member newsletter and occasional publications on hot topics affecting the profession: www.topra.org/resources

Regulatory Rapporteur
APRIL 2019
THE INTERNATIONAL JOURNAL FOR PROFESSIONALS IN REGULATORY AFFAIRS

EXPLORING NEW HEALTH TECHNOLOGIES

We investigate some of the new and emerging technologies used in healthcare

CPD with Regulatory Rapporteur
2019
TOPRA

BIOSIMILAR PRODUCTS: Regulatory complexities and challenges of biosimilars

The continuing professional development (CPD) supplement focus on the regulatory complexities and challenges associated with biosimilar products and their development. Although biosimilar products have been regulated and approved for use in the EU for more than a decade, there is increasing speculation and excitement on the potential for biosimilars with increasingly complex structures, eg, multi-subunit, extensively post translationally modified, and lipid-containing products.

Biologics cannot be referred to as generics, a term applied to pharmaceutical products denoting "sameness" with products

CPD with Regulatory Rapporteur
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TOPRA InTouch

MARCH 2019

THE TOPRA NEWSLETTER - KEEPING MEMBERS IN TOUCH

In this issue...

- Looking towards the future**
NICK SPEYS, TOPRA PRESIDENT
- CPD with Regulatory Rapporteur**
2019
TOPRA

TOPRA SUMMIT
CHANGE | CHALLENGE | FUTURE
23 MAY 2019 | LONDON
FIND OUT MORE

Regulatory Rapporteur

Our technical, peer-reviewed international journal for regulatory professionals is published 11 times a year. Members can opt to have the print version or access the online version via an alert each month as well as search an online archive.

CPD Supplements

Topic-focused continuing professional development articles are published quarterly as a supplement in *Regulatory Rapporteur*. You can also access them online and complete the CPD quizzes accompanying each one.

InTouch

Our monthly newsletter provides member-focused news with the latest updates from the TOPRA President, SPINs, TOPRA In groups, and more.

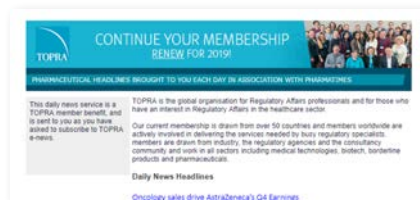
MY RESOURCES

Updates and news

Members can opt to receive a variety of eNewsletters across different sectors. Make sure you update your Member preferences to receive all our resources.

Daily News Feed – Pharma Times

All members can receive this daily news alert from *Pharma Times* to keep up with developments from around the world.



Vetmed Update

A monthly digest of news and information related to veterinary medicines.



MedDev Update

New! The latest official information and news on the MedDev and IVD sectors sourced each month with TOPRA members in mind.



NEW! Life-Lines – Keep Up To Date With Brexit

Fortnightly regulatory news from a legal perspective on Brexit developments.



‘TOPRA brings the level of regulatory information that I need and helps keep a meaningful professional community together’



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