Role of Regulatory Affairs Globally

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RAPS
REGULATORY AFFAIRS
PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

Objectives

- RAPS & Regulatory Affairs Community
- Update on Key Discussions at EU Conference
- Regulatory Affairs Professional's Profile

RAPS and Regulatory Affairs Community

Overview

- Established in 1976
- Non-political, independently funded, not-for-profit
- Headquartered in metro Washington, DC
- Chapters and affiliates throughout North America, Europe, Asia and Latin America

Mission

Develop and sustain a competent global regulatory workforce that drives good regulatory practice and policy to advance public health.

Members

- 24,000 individual members in 82 countries
- From industry, government, research, academic and clinical organizations
- Involved with medical devices, drugs, biologics, IVDs and other regulated healthcare products

Strategic Priorities

1. Proactively address evolving regulatory competencies required for the global profession
2. Deliver valuable and accessible learning and professional development experiences
3. Inform regulatory professionals of complex and evolving healthcare product regulatory developments
4. Empower a community focused on interactions, relationships and knowledge-sharing

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Changing Regulatory Landscape

Seismic shifts in the medtech and pharma sectors

- Patient-centricity, digital therapies and connected care
- Shift from treatment to prevention
- New therapies, advances in technology, data intelligence

Biopharma

- Real-world evidence, adaptive and seamless trial designs
- Complex supply chains require effective quality control and assurance
- Advances require streamlined regulatory processes to keep up with promising new discoveries
- Patient access to data and technology

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Medical Devices

- Shift from conventional manufacturing to integration of data intelligence
- New regulations (i.e. EU MDR) are demanding—but perhaps not as dramatic as feared
- New market entrants—disruptors, partners, enablers
- Brexit likely to bring new complexity and duplication

The Regulatory Profession

As regulatory leaders, we must:

- Be engaged and stay attuned to ongoing developments
- Provide the best analysis and advice on changing regulations and new technologies
- Bring clarity—even when no clear answers exist
- Maintain a problem-solving mindset

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Regulatory & Innovation

- “The pace of innovation in medical devices has surpassed medicines due adaptable approaches to the regulation of innovative products. While the existing novel licencing pathways for medicines have seen positive results in providing timely patient access, current and upcoming innovations will continue to challenge regulators,” - *International Coalition of Medicines Regulatory Authorities (ICMRA)*

Update on Key Discussions at EU Conference

EU Medical Device Regulation (MDR) Combination Product Changes

- EMA Guidance on MDR Article 117
  - Applies to medicinal products with integral device component
    - Medicine and device for a single integral product
    - Intended exclusively for use in a given combination
    - Not reusable
  - Requires medical device conformity assessment against MDR Annex I *General Safety and Performance Requirements* (GSPR)
    - Declaration of conformity
    - CE certificate
    - Notified body opinion

EU Medical Device Regulation (MDR) Combination Product Changes

- EMA Guidance on MDR Article 117 (continued)
  - Address in device part of marketing authorization
  - Medicinal marketing authorization applications from 26 May 2020
  - No requirement for retrospective application to existing MAs or MAAs submitted before 26 May 2020
  - CE certificate or NB opinion required with appropriate variation/extension application following substantial change or new device

EU Medical Device Regulation (MDR) Combination Product Changes

- EMA Guidance on MDR Article 117 (continued)
- Collaboration with stakeholders on implementation
  - EMA stakeholder interested parties meetings
  - Medicines authorities and device authorities
  - Regular exchange with the European Commission (GROW/SANTE)
  - Informal exchange with notified bodies (two designated under MDR)

EU Medical Device Regulation (MDR) Combination Product Changes

- EMA Guidance on MDR Article 117 (continued)
  - Draft guidance and Q&As
  - EMA medical devices website
  - Other issues
    - Medical devices with ancillary medicinal substances
    - Companion diagnostics under EU IVDR
    - Devices composed of substances systemically absorbed
    - Borderline products
  - Draft guideline for public consultation by Q2 2019

EU Medical Device Regulation (MDR) Combination Product Changes

- Medical devices incorporating ancillary pharmaceutical substance
- Medical Device Directive (MDD) required NBs to submit to consultation medicines CA
- Possible* scenarios for re-consultation under MDR
  - No need for re-consultation
  - New consultation
  - Re-consultation based on limited post market data
  - Re-consultation based on medicines renewal procedure

  **personal views of senior one medicines authority expert*
- Common EU approach needed
- What about Brexit – Largest number of medicines consultations conducted by UK MHRA

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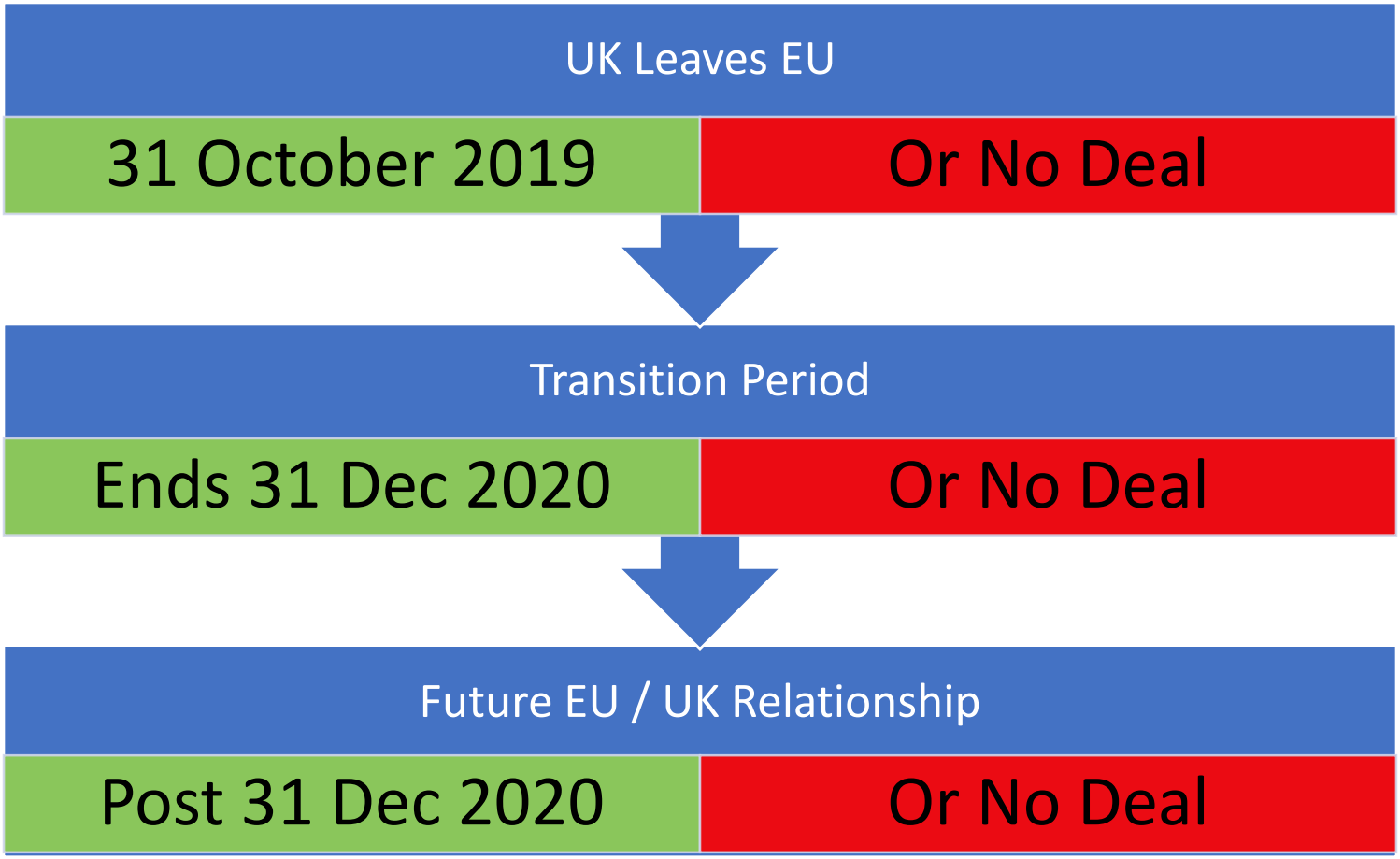
Brexit

- Deal or no deal
- EMA moved from London to Amsterdam
  - Some loss of staff
- 2019 exit
  - 29 March? 12 April? 31 October – anytime before
- Deal and no deal scenarios in place

Brexit Roadmap



Brexit & Pharmaceuticals

- Current ‘deal’ is ratified
  - 2 year implementation period
  - Details clarified during implementation period
  - Continued market access until December 2020 under common rules
    - Mutual recognition of batch release QP certification
    - Centrally Authorized Product license valid EU and UK
- Current official positions
  - EC and EMA – UK will become a ‘third country’ unless a ratified agreement is established
  - MHRA – UK aims to operate a medicinal regulatory procedures aligned with EU

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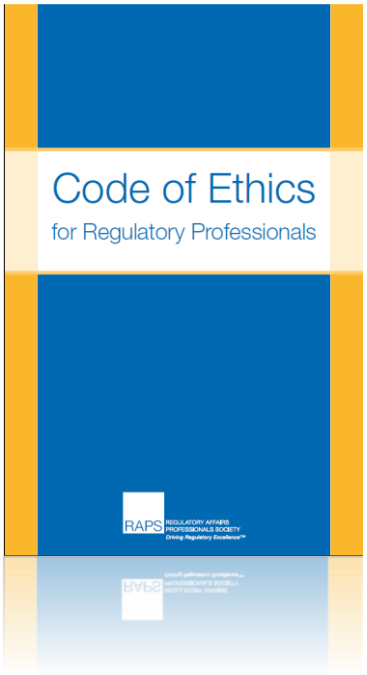
Regulatory Affairs Professional's Profile

Navigating the Gray

- We can't wait until we have all the answers
- We won't get everything perfect
- Sometimes we'll do more than was strictly necessary; sometimes less than what's required
- We'll need to recalibrate and adjust along the way
- We will learn, grow, continually improve

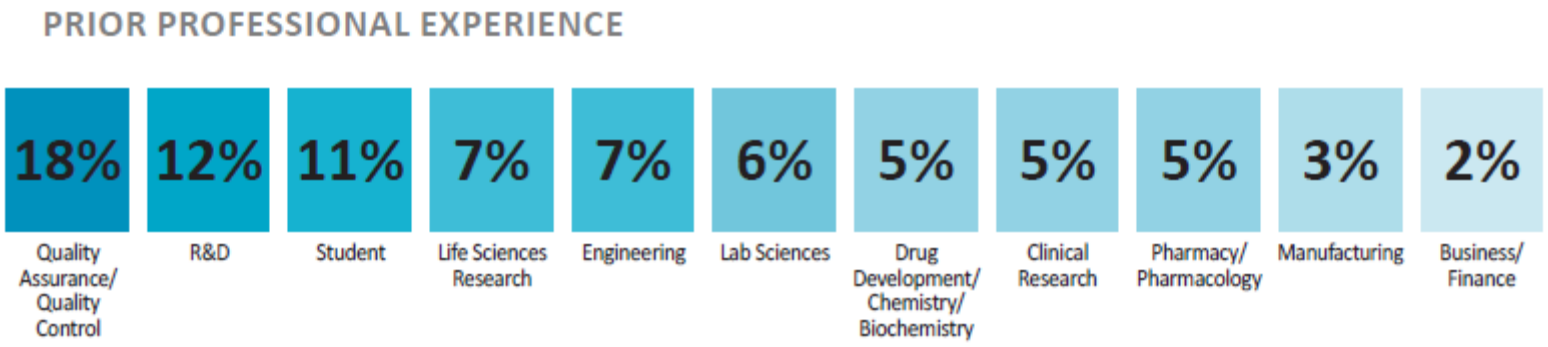
Code of Ethics



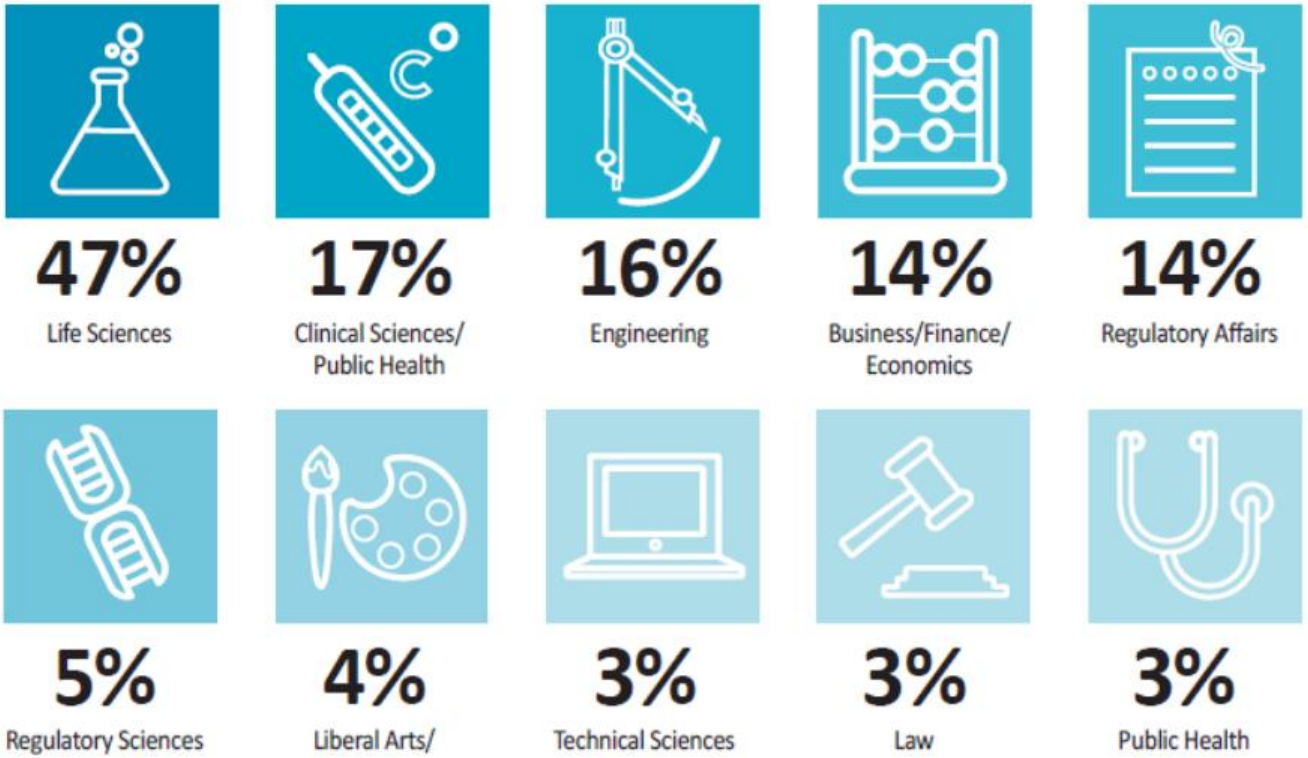
- Developed for regulatory professionals *by* regulatory professionals
- Comprised of global input across diverse product sectors
- Exists as an aspirational guiding code; not enforced as a condition of RAPS membership

Regulatory Scope of Practice

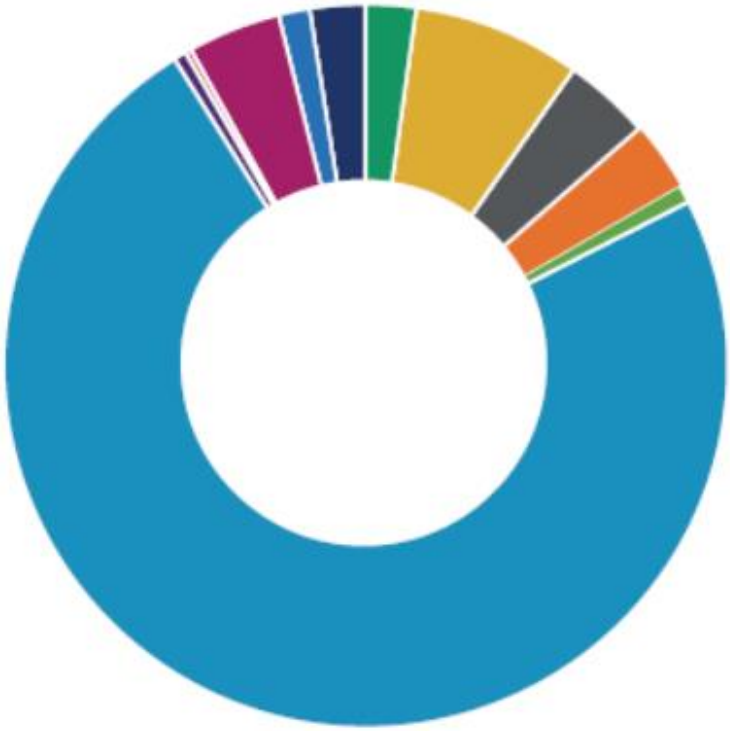
Transitioning into Regulatory



Educational Background



Work Setting

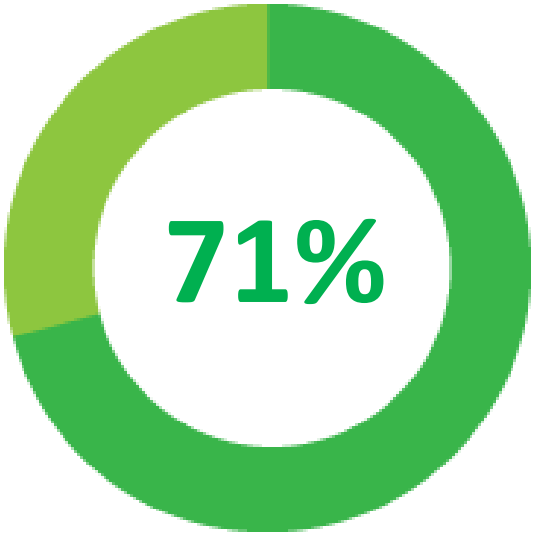


Academic Institution	2.3%
Consulting	7.6%
Clinical Research Organization	3.8%
Government	3.0%
Hospital/Medical Practice	0.9%
Industry	73.6%
Laboratory	0.5%
Notified Body	0.4%
Self-employed	4.2%
Not-for-Profit Association	1.4%
Other	2.3%

Responsibilities and Time Spent

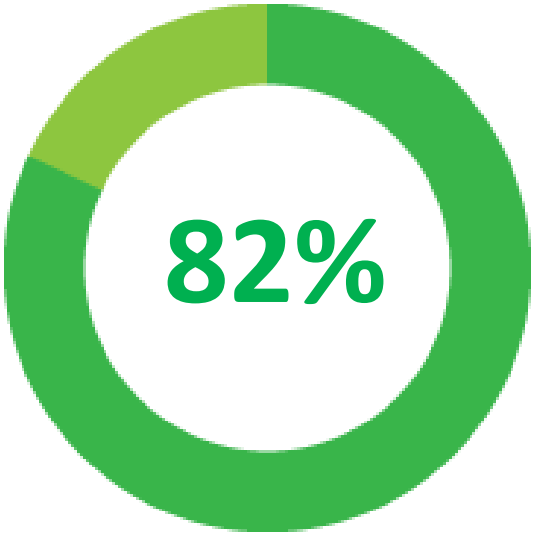
Business Related	11.4%
Regulatory Intelligence and Strategy	21.7%
Preapproval/Approval	17.8%
Postapproval	30.0%
General/Full Product Lifecycle	17.4%
Training	1.4%

Rising Visibility



71% report that executive management is aware of the strategic importance the regulatory function has within their organization

Increasingly Involved



82% are directly involved with shaping strategic and business directions within their organizations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CERTIFICATION
RAC DEVICES


REGULATORY AFFAIRS
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CERTIFICATION
RAC DRUGS

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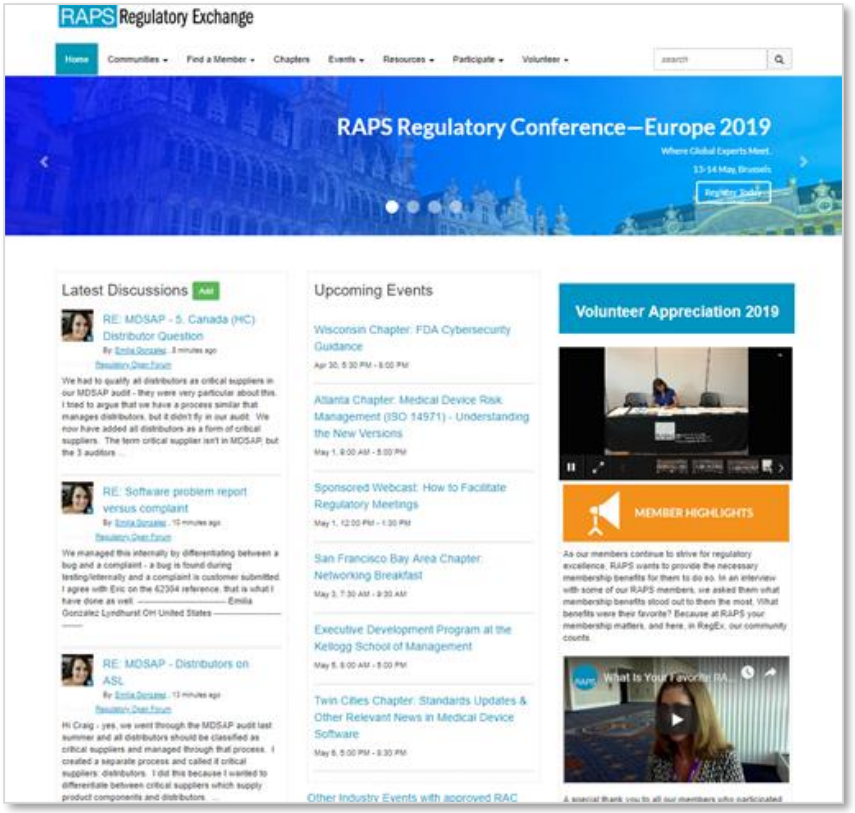
RAPS Community



Regulatory Exchange: Connect with peers from around the globe

The source for the latest regulatory news and information

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CAPRA and RAPS

- CAPRA has been a regular participant in RAPS Convergence
- Collaborated to bring Canadian regulators and experts to the 2018 Convergence in Vancouver
- Worked together on content for two RAPS publications on Canadian regulatory affairs:
  - Medical devices
  - Pharmaceuticals and biologics

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CONVERGENCE
21–24 September 2019
Philadelphia