JANUARY 2021

**Topic** Impact of Disruptions on the Global Regulatory Community  
**Lead** Mary Speagle, RAC  
**Description** Impact of disruptions, for example, COVID-19, on work style; remote/smart working; how to improve technology usage; communication; working within your company vs with outsiders; third party reviews; developing the next generation of staff; finding new employment during COVID; impact on global RA; best practices for meeting remotely with health authorities; comparison of onsite to virtual GMPs; change control; supply change. Are regulators on board? What will the ‘new normal’ look like?  
**Articles due** 31 December 2020  
**Publication** Throughout January 2021

FEBRUARY 2021

**Topic** Global Regulatory Harmonization  
**Lead** Orin Chisholm, GCULT, PhD, MTOPRA  
**Description** Harmonization, convergence and reliance are becoming increasingly important in regulatory affairs. As molecules become more complex, the boundaries between different types of therapeutic products blur and national regulatory authorities (NRA) are stretched with the necessary expertise to review all these new product innovations. One response by NRAs is to develop work-sharing arrangements and some of these initiatives will be covered in this topic. However, work-sharing cannot occur without international adoption of technical standards, so we will also examine the progress occurring in this area, particularly with respect to adoption of ICH standards globally. Looking to the future, harmonization will be greatly facilitated with the adoption of international standards for data, so we will review what is happening in this space as well. Companies need to be aware of these arrangements and take advantage of them in defining their regulatory strategy in order to facilitate timely access to their new products globally.  
Article topics could include:  
- ICH guidelines and their global adoption (eg, GCP, multiregional clinical trials, etc)  
- PIC/S efforts at harmonizing and standardizing GMP  
- Work-sharing between NRAs: ACCESS and Project Orbis  
- Regional harmonization and reliance schemes – African harmonization initiative, ASEAN, APEC initiatives  
- Harmonization initiatives for medical devices such as IMDRF, MDSAP  
- Harmonization of advanced therapies such as cell & gene therapy products – what is/should be done?  
- International data standards and their implementation in regulatory affairs  
**Articles due** 15 January 2021  
**Publication** Throughout February 2021

MARCH 2021

**Topic** Regulatory Intelligence  
**Leads** William Sietsema, PhD, and Linda Bowen, MSc, RAC, FRAPS  
**Description** Overview of RI; best practices; communicating in RI; regulatory precedence; sources of RI (toolbox, incl. precedence, FOI); profiling regulator staff and committee members; surveillance and monitoring techniques, RI metrics; RI skill sets; building an RI department; RI databases – home grown and subscription; the future of regulatory intelligence.  
**Articles due** 1 February  
**Publication** Throughout March

MARCH 2021 – Spring RF QUARTERLY

**Topic** Global Clinical Trials  
**Lead** Editorial Advisory Committee  
**Possible topics**
- Experience with the EU Voluntary Harmonization Procedure
- Preparations for the EU Clinical Trials Regulation coming into force
- Implementation of the FDA guidance (June 2020) on patient-focused clinical development
- How to get alignment of FDA, EMA, and PMDA on global registration trials
- Reporting clinical trial changes to the FDA during the COVID-19 pandemic
- Ensuring diversity clinical trials
- Approaches to first in human trials for rare/ultrarare diseases (especially with gene or cell therapy)

**Articles due** 5 February 2021

**Releases** 15 March

**APRIL 2021**

**Topic** Regulatory Career Development

**Leads** David Husman, PhD, ASQ, CPGP, RAC and Peter Takes, PhD, RAC

**Possible topics**

- Working in a regulated environment – what does that mean?
- Technical knowledge vs. compliance mindset
- Pathways to regulatory affairs – college; new hire; transition from other departments (quality, research, production, technical services, marketing)
- Credentialing – perspectives from RAC members
- Specializing in RA – submissions (domestic, global), clinical, commercial, labeling, compliance
- Life as a regulatory professional – Small and large companies, consultant
- Transitioning product lines/specialties
- Transitioning from specialist to manager to director to VP
- Reaching beyond your company – contributions to the profession

**Articles due** 1 March 2021

**Publication** Throughout April

**MAY 2021**

**Topic** Update on the EU IVDR and MDR

**Leads** Gert Bos, PhD, FRAPS, and Sue Spencer, BSc (Hons)

**Description** With the Date of Application for the MDR set for 26 May 2021, articles in this issue will explore state-of-art interpretation on MDR compliance. Clinical, biocompatibility, and toxicity need to be covered in more depth, and many administrative changes will need to be put in place, such as assigning the PRRC, registering in EUDAMED, etc. What should be ready on the 26th? In regard to IVDR, its 2022 Date of Application seems far away, but as most products cannot apply the grace period, the remaining 1 year will largely be absorbed by the Notified Body conformity assessment. Articles on this topic will look at avoiding last-minute panic and aiming to be ready sooner, rather than later.

**Articles due** 1 April

**Publication** Throughout May

**JUNE 2021**

**Topic** Nutrition in Health and Disease Management, and the Gut Microbiome

**Leads** Manfred Ruthsatz, PhD, RPh, DABT, RAC, FRAPS and Andrea Wong, PhD

**Description** 2021 marks the 6th annual RAPS series on nutrition in health and disease management, augmented by articles on the gut microbiome. Authors and reviewers, who are global leaders in their respective areas of specialty and expertise, produce a line-up of in-depth articles on food, specialized nutrition, personalized nutrition, and dietary supplements from regulatory, trade, marketing, and legal standpoints across the globe.

**Articles due** 3 May

**Publication** Throughout June

**Q2 RF QUARTERLY – Artificial Intelligence (June)**

**Topic** Artificial Intelligence
**Leads** Gert Bos, PhD, FRAPS, and Koen Cobbaert, MSc
**Articles due** 22 March
**Releases** 1 June

**JULY 2021**
**Topic** Real-World Evidence and Data
**Lead** Daniel Mannix, PhD,
**Description** Success stories, case studies
**Articles due** 19 July
**Publication** Throughout July