Insights from Industry Leaders

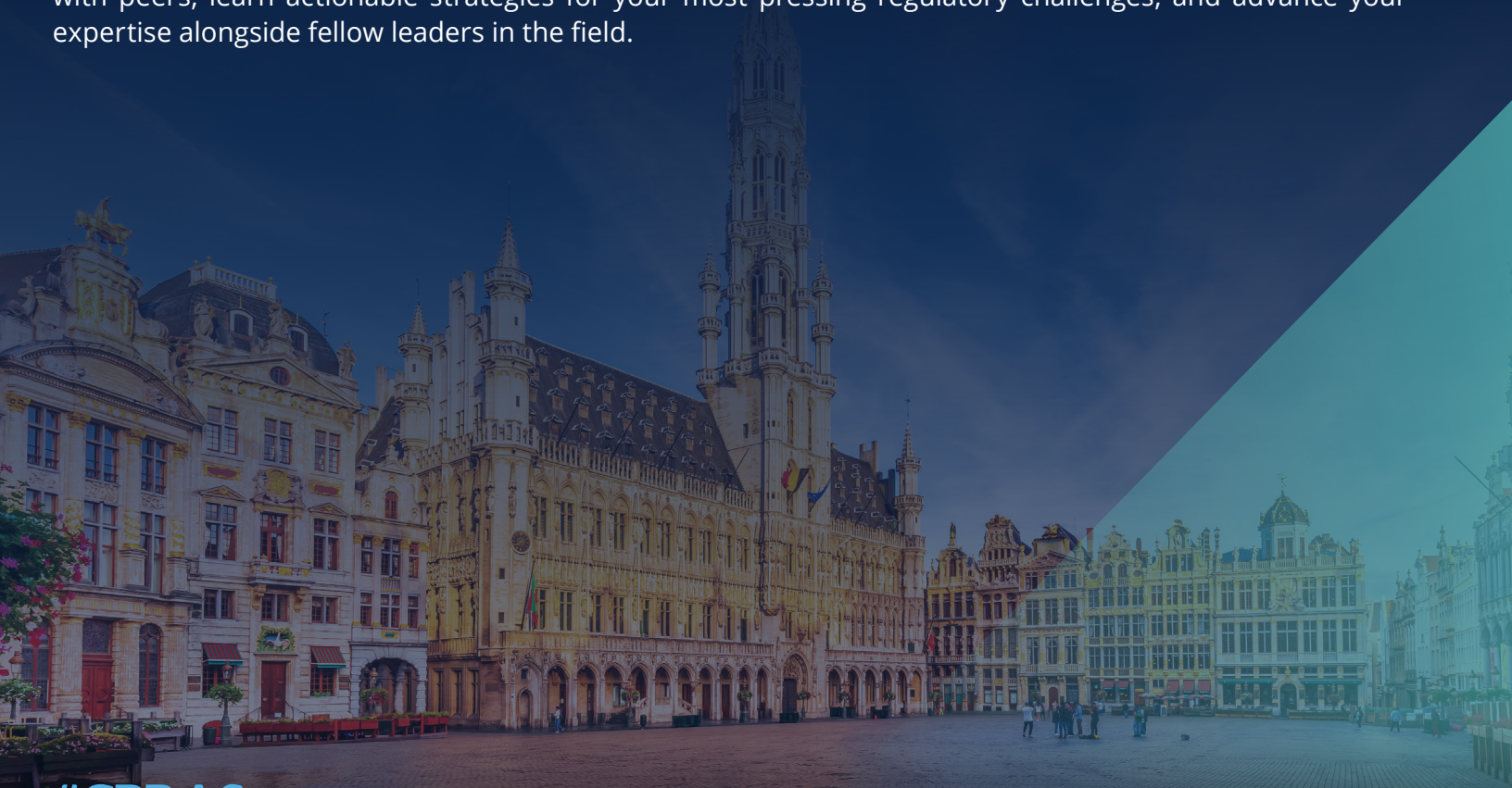
Global Pharmaceutical Regulatory Affairs Summit

by informa

28-30 September 2026
Radisson Brussels Grand Place
Brussels, Belgium

In an increasingly complex regulatory landscape, pharmaceutical professionals must navigate evolving standards, digital transformation initiatives, and the shift towards data-centric operations. The Global Pharmaceutical Regulatory Affairs Summit (GPRAS) 2026 brings together regulatory authorities, industry leaders, and regulatory affairs professionals to address the most pressing challenges shaping the future of pharmaceutical regulation. This exclusive Q&A document offers insights directly from our distinguished Advisory Board members — seasoned experts at the forefront of regulatory information management, IDMP implementation, and digital transformation.

Whether you're focused on optimising regulatory information management, implementing global eSubmissions strategies, or building the data capabilities needed for tomorrow's regulatory environment, these expert perspectives provide a valuable preview of the critical discussions taking place at GPRAS 2026. Join us on 28-30 September 2026 at the Radisson Grand Place in Brussels, Belgium, where you'll connect with peers, learn actionable strategies for your most pressing regulatory challenges, and advance your expertise alongside fellow leaders in the field.



#GPRAS

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Speaker Q&A Highlights

Remco Munnik

Founder & Consultant,
Arcana Life Science Consulting, S.L.

1. **How did you get into your current role? What drives your passion for the work that you do today?**

   I entered regulatory affairs almost by accident 25+ years ago. Started with Application Forms and page numbering.

   Continued into submission procedures, electronic formats (eCTD), data structures and systems (RIM). I was there when the EU Telematics environment was formed and when many standards moved from concept to implementation, and I saw firsthand how much value gets lost when regulatory data is treated as paperwork instead of an asset. That's what drives me.

2. **From your experience, what is the single biggest operational challenge facing regulatory teams today?**

   Fragmentation. Not a lack of systems, if anything most companies have too many, but a lack of a single source of truth for regulatory data. Teams still maintain the same product information in five different places and reconcile it manually before every submission. Every new standard, IDMP included, gets bolted on top.

3. **How prepared do you think the industry is for upcoming regulatory and standards changes, and what should organizations prioritize over the next 12-24 months?**

   I think we're at a pivotal moment: companies realize IDMP is here and that related data standards are coming, and at the same time the EU network is moving toward a data-first approach to regulatory submissions. That combination changes the game. Companies that keep treating this as a documentation exercise will fall behind those that start treating regulatory data as the primary asset, with documents as just one output of it.

   Therefore, I would prioritize three things: get product data into a structured, standards-ready format now, don't wait for a final mandate; build internal ownership of regulatory data quality; and invest in people who understand both the regulatory intent and the data structure. That combination is rare, and it's the bottleneck.

4. **How would you advise organizations to balance innovation with compliance and strong data governance?**

   My advice: stop treating them as opposites. The organizations that get this right build governance into the innovation, not around it. If you're piloting an AI tool for submission authoring or a new RIM system, your data governance rules should be part of the pilot design from day one, not a gate you hit at the end.

5. **Why is it important for you to attend GPRAS? What value do you gain from attending?**

   GPRAS is the EU conference dedicated to regulatory operations. You get the latest information and the chance to speak to peers and align. It puts the right mix of regulatory, data, and operations people in one room, and that's genuinely hard to find elsewhere.

6. **What is it about GPRAS that makes you want to return year after year?**

   The information as received during the sessions give a good update on the latest and greatest. The conversations between the sessions are even better.

Frits Stulp

Chairman of the Board,
CTADHL

1. **How did you get into your current role? What drives your passion for the work that you do today?**

   I have been in the area of digitalization of regulatory for 15 years now, after working most of my career in process optimization and information management in life sciences. I strongly believe that the strength of our assessment and approval processes in life sciences should match the strength of the science of our medicinal products. However, we often still rely on very old-fashioned ways of working together and I am passionate about making data the superfuel to make these processes work better and bring people together to adopt and improve this.

2. **From your experience, what is the single biggest operational challenge facing regulatory teams today?**

   The diversity in ways of working with the many portals, different submissions and lack of one version of the truth for your product (both internally and externally) poses a continuous challenge with many work arounds and errors. And this if often at the expense of getting products (or updated product information) to the patient.

3. **How prepared do you think the industry is for upcoming regulatory and standards changes, and what should organizations prioritize over the next 12-24 months?**

   Many companies focus strongly on applying AI for efficiency and cost reduction purposes, which is understandable. But in my view, this introduction should go hand in hand with the closer way of working with the regulator (and your other partners in this field, like CROs and license partners) using a common set of defined product data as well as a cloud environment to perform better.

4. **How would you advise organizations to balance innovation with compliance and strong data governance?**

   There is no innovation achievable if you can not guarantee compliance and data governance, but at the same time, data governance and compliance alone will not make you successful in this quickly changing world. Therefore, business requirements (also based on evolution of standards, technology and legislation) should drive this in an agile way while reaping benefits along the way. It takes strong leadership and longer term vision and not just focus on the here and now.

5. **Why is it important for you to attend GPRAS? What value do you gain from attending?**

   Connecting with the many professionals in this field is always key and thereby seeing where we can jointly move the dial most!

6. **What is it about GPRAS that makes you want to return year after year?**

   It is the European regulatory event of the year, so let's make sure the contents are there to bring people together.

Laurent Desqueper

Digital Technology Lead Intelligent Content Generation,
UCB

1. **How did you get into your current role? What drives your passion for the work that you do today?**

   I'm an IT person who never wanted to do IT... because IT is useless if it does not support a business need. That's why I always try to be a middleman between regulatory IT and regulatory business to progress the regulatory digitalization in pharma industry, in close collaboration with Health Authorities, to remain compliant, and be more efficient with our industry processes.

2. **From your experience, what is the single biggest operational challenge facing regulatory teams today?**

   Regulatory has been in a steady state for the last 20 years (e.g., eCTD 3.2) and will face numerous changes in the coming 5 years. The main challenge won't be to implement our internal systems and processes to adhere to these new regulatory requirements, but instead to efficiently support the transition as countries/markets will be evolving at different speeds throughout the coming 10 years.

3. **How prepared do you think the industry is for upcoming regulatory and standards changes, and what should organizations prioritize over the next 12-24 months?**

   Industry is preparing but there is a high level of uncertainty on the Health Authority approach for data-driven submissions, or the balance between innovation (the power of AI), regulatory compliance (the controls needed), the agile programs (like the EMA SPOR program), and our internal budget cycles.

4. **How would you advise organizations to balance innovation with compliance and strong data governance?**

   Innovation is tempting, especially the power of AI, but "Human-in-the-Loop" is not a reason to descope the compliance requirements. Therefore, I would advise remaining on the safe side when implementing innovative solutions to address regulatory requirements. That might look conservative or even old-fashioned, but that's the only approach to remain compliant.

5. **Why is it important for you to attend GPRAS? What value do you gain from attending?**

   GPRAS is a unique place where many topics are addressed in regulatory digitalization. This is an opportunity to connect with industry peers and exchange our practical experiences. This is also a great place to meet vendors and query the maturity of the market regarding the coming innovations

6. **What is it about GPRAS that makes you want to return year after year?**

   What I'm looking for (connection with industry peers, update on regulatory digitalization, update on the vendor market...) is achieved year after year, and the main reason to come back again and again.

Quentin Darrasse

Data Strategy Principal,
Roche

1. **How did you get into your current role? What drives your passion for the work that you do today?**

   Improving the management of regulated information has been my area of focus for over a decade. The fast development of technologies makes this journey fascinating and full of learnings.

2. **From your experience, what is the single biggest operational challenge facing regulatory teams today?**

   Digital transformation, and especially the shift to a data-centric operating model within Regulatory Affairs as well as Company-wide, is a substantial opportunity to improve our business operations, but it also has demonstrated to be a long transition, with peaks and valleys.

3. **How prepared do you think the industry is for upcoming regulatory and standards changes, and what should organizations prioritize over the next 12-24 months?**

   I believe that there is a big opportunity for Regulatory Affairs to drive digital transformation across the Pharmaceutical Industry, and that by taking such an opportunity, compliance is a given. Notably, building today the data capabilities that will enable us to operate better tomorrow, such as federated data integration layers, or seamless information exchanges across business ecosystems, should be a priority.

4. **How would you advise organizations to balance innovation with compliance and strong data governance?**

   Proactively shifting to better data-driven ways of working facilitates continuous compliance by design. I think that Regulatory Affairs departments should not wait for compliance requirements to transform their operations.

5. **Why is it important for you to attend GPRAS? What value do you gain from attending?**

   GPRAS is the most relevant forum in Europe when it comes to Regulatory Information Management. I have been attending GPRAS almost every year for over a decade, as it has always demonstrated to be one of the best place to connect with my peers and to get valuable insights in regards to every hot topics of the moment.

Patrick Middag

Principal Regulatory Affairs Lead,
Servier

1. **How did you get into your current role? What drives your passion for the work that you do today?**

   As a technologist by passion and training, I have led digitalization initiatives in pharmaceutical R&D for more than 25 years. After spending just over a decade keeping IDMP high on the Regulatory Operations agenda, I have recently transitioned into a role with a stronger focus on RIM processes.

2. **From your experience, what is the single biggest operational challenge facing regulatory teams today?**

   In our company, the biggest operational challenge is keeping pace with the rapid digital evolution while remaining competitive and agile enough to adapt as strategy shifts and the global regulatory environment evolves. Operational efficiency is being pursued through several levers, including process optimization, outsourcing, and expanded digital capabilities.

3. **How prepared do you think the industry is for upcoming regulatory and standards changes, and what should organizations prioritize over the next 12-24 months?**

   I observe that many companies are still addressing data quality issues and process inefficiencies by adding resources or expecting AI to solve the problems. However, as long as regulatory business remains largely document-centric, this is little more than a temporary fix. I believe real change requires a data-first mindset, supported by structured data, semantic knowledge graphs, and more deterministic, auditable AI to unlock data potential for regulatory and operational needs. In order of priority: 1) focus on sound data management, data governance, and data quality; 2) structured authoring; and 3) “beyond experiment” AI for data-centric content operations.

4. **How would you advise organizations to balance innovation with compliance and strong data governance?**

   As noted in question 3, a data-first mindset, supported by strong data management, data governance, and data quality, must provide the foundation for innovation through advanced AI capabilities. The Regulatory Data Office should not focus solely on operational activities, but also establish the strategic foundation and direction needed to support and enable innovation. Without this, AI will not progress beyond experimentation and will simply amplify poor-quality inputs.

5. **Why is it important for you to attend GPRAS? What value do you gain from attending?**

   GPRAS has become my most anticipated annual networking event. In Europe, it is the leading forum where key industry and vendor stakeholders come together to discuss the current state of Digital Regulatory, including challenges, opportunities, experiences, lessons learned, new ideas, pilots, and experiments. I hope to return with at least three new ideas that I can share within my organization

6. **What is it about GPRAS that makes you want to return year after year?**

   The event offers an excellent balance between networking and learning, with valuable perspectives from industry, regulators, and vendors. The limited commercial bias makes the discussions more substantive and focused on practical experience, shared challenges, and meaningful progress across the Digital Regulatory landscape.