Post-event Report 2020: Global Pharmaceutical Regulatory Affairs Summit

Executive summary and panel discussions

Global Pharmaceutical
Regulatory Affairs
Summit

Introduction & Contents

Welcome...

Thank you to all the delegates, speakers and sponsors who supported the virtual Global Pharmaceutical Regulatory Affairs Summit.

The pandemic has created many challenges and a new way of life for many; this year's virtual conference was one of the many changes 2020 has brought. However, my deepest thanks go to all those who attended the virtual Summit and continued to engage with the speakers, sponsors and fellow delegates in this new format.

Global Pharmaceutical Regulatory Affairs Summit has been going for many years, covering some of the hottest topics in telematics, eCTD and global regulations. At each conference, we strive to bring regulatory experts from across the pharmaceutical field to discuss the latest challenges in market access, regulatory management and pharmaceutical submissions. With regulatory strategies changing in the wake of the global pandemic and the move to create a more digital data driven regulatory structure, bringing experts from the different sectors of regulatory affairs is more crucial than ever.

With IDMP version 1 being released in February of this year, it was interesting to hear the impact this will have on industry and what steps are needed for industry to prepare for implementation. Whereas, in the global markets stream it was excellent to have regulatory agencies ANVISA and Russia present. With Brazil and Russia being two of the biggest regulatory markets at the moment getting the latest updates straight from NCA representatives was invaluable.

I have many personal highlights of this event, but the standout for me is the willingness of the speakers to throw themselves into a brand-new event format and continue to provide vital information to the delegates. With the world of virtual conferences with us for much longer than any of us had originally imagined, this enthusiasm has confirmed to me that in these strange times, we will still be able to create environments where the industry can learn from each other and continue to create a regulatory system with the main aim of getting new products to patients as quickly and efficiently as possible.

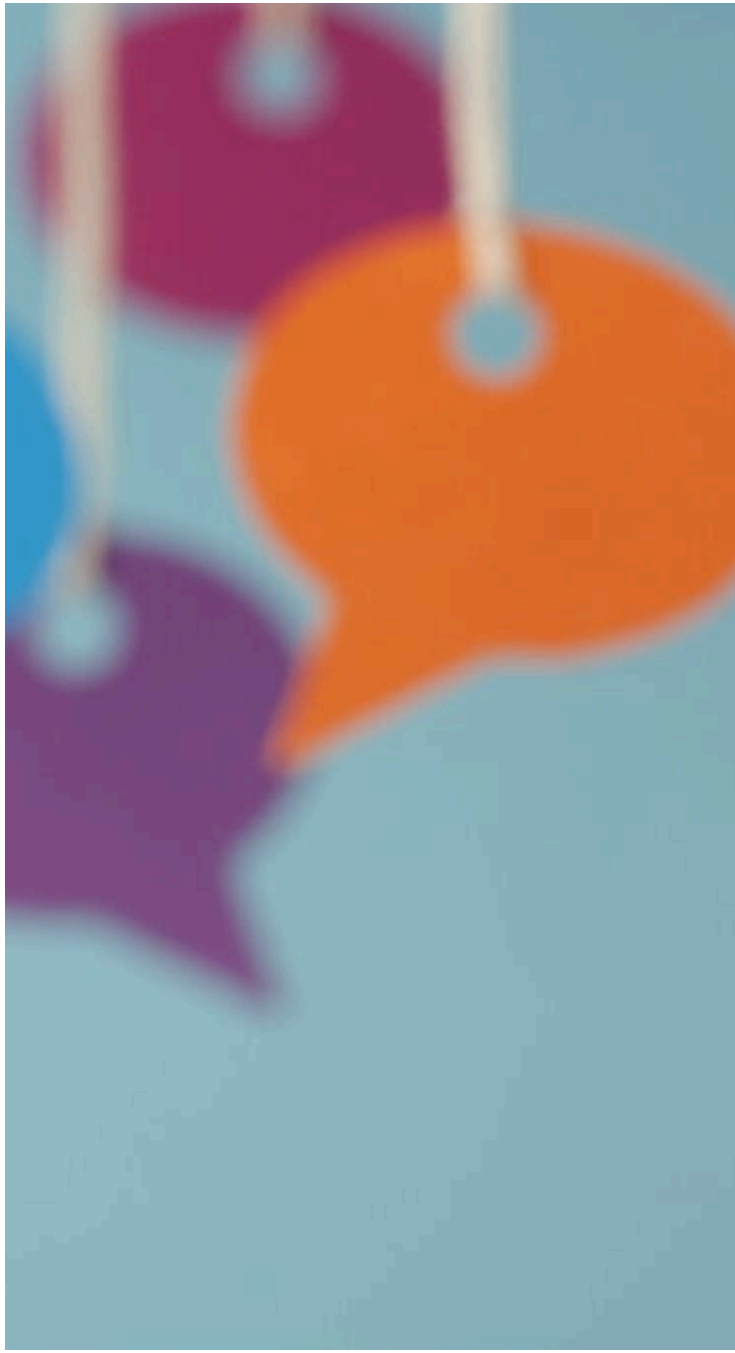
I hope you find this post event wrap of the event useful, and I look forward to seeing many of you at our 2021 conference.

Stay safe and well,

Rebecca Brady,
Senior Conference Producer,
Global Pharmaceutical Affairs Summit

Jump to any article using the contents on the following page, or at any time using the Contents menu in the top left. There you can also download this report as a PDF.

Contents



The Event at a Glance...

Statistics from the week

A look back at Global Pharmaceutical Regulatory Affairs Summit 2020...

	TOTAL
Delegates	133
Speakers	55
Sponsors	23
Sessions	84
Meetings	29
Questions answered	235
Messages sent	1680

This year's Global Pharmaceutical Regulatory Affairs Summit was delivered 100% virtually for the first time ever.

It brought together a spectrum of innovators in the field to provide the latest insights, panel discussions, interactive Q&As and debates, both live and on-demand.

Outside its usual physical setting, the virtual experience provided live labs, networking rooms and automated matchmaking.

The diverse audience included representatives of industry and regulatory health authorities from a variety of global regions.

Key Themes of the Week

Executive Summary

Across the week, presentations and discussions revealed the latest strategies and processes driving transformation of pharmaceutical regulatory affairs around the world.

From e-Submissions and harmonisation across different regions to RIMS and optimising data management, the sessions covered a wide range of hot topics.

Medical and Regulatory Researcher and Writer **Zoya Marinova** provides an overview of the three main themes addressed by top presentations in each conference track.

Key Themes of the Week - Executive Summary

Regulatory Affairs in Global Markets - Asia, Latin America, and Russia

Regulatory reform and the drug approval process in China: where are we now?

Ching Li, Regulatory Manager, Biotest Pharma GmbH

Ching Li described the modernisation of the regulatory approval process in China since the amendment of the Drug Administration Law and the implementation of the new vaccine administration law on 1st December 2019. Recent changes include provisions for drug registration regulation (DRR) and for the supervision and administration of drug production GMP, a draft for variation guidelines, and a pilot programme for breakthrough, conditional, and priority regulatory procedures. Further expected milestones include the drug category submission requirements for CTD and the Chinese Pharmacopeia.

The Drug Administration Law was first enacted in China in 1984 and underwent its second major amendment in 2019. It has been expanded into 155 articles in 12 chapters and aims to establish a scientifically sound and strict supervision and administration system, to promote risk management, and to ensure drug safety and quality. The amended law focuses on innovation, encourages clinical value-oriented R&D, and regulates the overall process of management and control (GxP).

Li then explained how the revised drug registration regulations address the implementation of drug innovation. Applicants have been expanded to R&D entities that can bear the corresponding legal responsibility. Moreover, the responsibilities of national and provincial regulatory agencies have been clarified, the regulation has been brought in line with international rules, and the review and approval process has been optimised. The adherence of the Center of Drug Evaluation (CDE) to these timelines was illustrated. In 2019, 90% of the applications were reviewed and approved by the CDE on time, and the backlog was reduced greatly. The number of applications to the CDE until July 2020 has increased by 15.4% compared to the same period in 2019, showing that the pandemic did not slow down the application process. Moreover, the CDE demonstrated the capacity to work efficiently under these exceptional circumstances.

Finally, Li showed how the pilot regulatory pathways for breakthrough designation, priority review, conditional approval, and exceptional circumstances function to encourage innovation. The priority pathway has received most applications with a focus on products with obvious clinical value that meet an urgent medical need and show clear advantages.

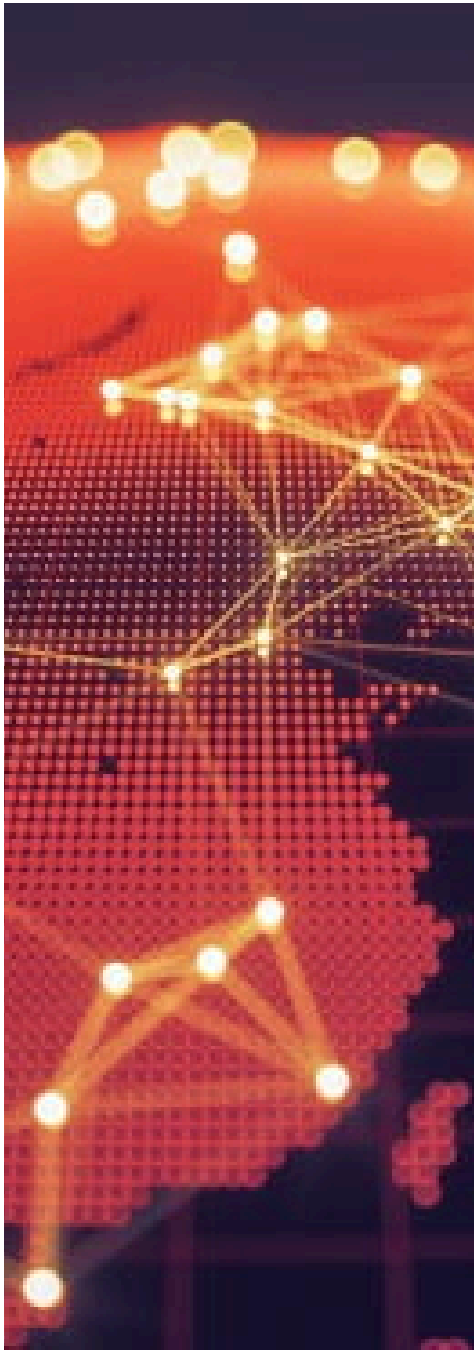
Regulatory strategy in EAEU and rest of CIS countries: points to consider for successful market access

Nargiz Asgarova, BSc, MBA, Regulatory Affairs Projects Manager, Biomapas

Nargiz Asgarova presented regulatory strategies for successful market access in the Commonwealth of Independent States (CIS) countries, focusing on the current situation, challenges, practical tips, and GMP requirements. Her presentation covered both the Eurasian Economic Union (EAEU) and NON-EAEU CIS countries.

The EAEU, which includes Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia, is moving toward a process of common EAEU Marketing Authorization Applications (MAAs). Beginning 1st January 2021, all new MAAs should be submitted according to the common EAEU information electronic portal (CIEP). However, national Marketing Authorizations (MAs) will remain valid until 2025.

Challenges currently faced by the EAEU include the interaction between HAs, lack of clear guidance for confidential information, submission of variations with RVP, different national duration of data exclusivity, and harmonisation of switching to the EAEU normative document



> "Challenges currently faced by the EAEU include the interaction between HAs and lack of clear guidance for confidential information."

requirements and upcoming EAEU Pharmacopeia. As of August 2020, there are 78 EAEU MAs. The COVID pandemic also poses a challenge by impacting GMP inspection procedures and clinical studies conductance.

The next focus of the presentation was the NON-EAEU CIS countries, including Azerbaijan, Georgia, Moldova, Mongolia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan. The differences in the regulatory processes of the countries were highlighted.

In 2020, different regulatory updates have been carried out in Azerbaijan, Ukraine, and Uzbekistan.

The national MAA timelines vary among the NON-EAEU CIS countries between 3 months and 15 months for the standard procedure and between 1 month and 6 months for the accelerated procedure. The accelerated procedure offers many advantages that may include a simplified dossier, a dossier identical to the reference country, reduced HA fees, or shorter review timelines. Challenges encountered during the regulatory process in the NON-EAEU countries include differences in the specific national regulations, the changing regulatory environment, different labelling requirements, or high-level requirements.

Finally, Asgarova described the GMP requirements in CIS countries. The EAEU is transitioning from national GMP certificates toward EAEU GMP certificates. The EAEZ CGM certification procedure includes a GMP inspection at the manufacturing site for compliance with EAEU GMP requirements, which should be obtained prior to the MAA or RVP and is valid for 3 years.

The fusion of IDMP into submission data

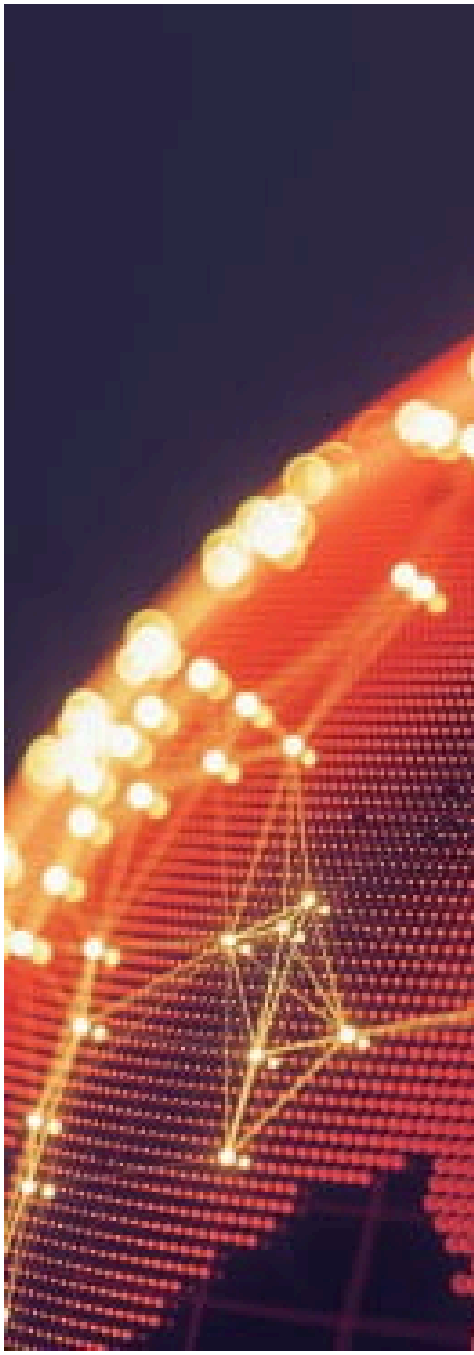
Dr Anna Thaidigsmann, Senior Business Consultant, EXTEDO

Dr Anna Thaidigsmann began her presentation by showing how the implementation of xEVMPD in 2014 has contributed to the introduction of DATA Only submissions and has served as a basis for PV fee calculations. She illustrated the business processing model for document submission and the role of xEVMPD in this process.

Her presentation showed that we are at a timepoint of increased fusion of IDMP and submission data, and the need for data exchange is boosted by a number of EU initiatives. Particularly, the IDMP serves as a link between the unstructured data of the SmPC and the semi-structured data of the eAF.

Defined, well controlled vocabularies (CVs) serve as the basis for DATA Only submissions. The role of CV usage in MAH with IDMP data sets, eAF, and backbone and content plan creation was illustrated, and an example of a real-life CV IDMP fusion was presented. Notably, different databases with high value sets may exist within a company. In these cases, business continuity and high data quality should be ensured before the fusion of data sets.

Finally, Dr Thaidigsmann summarised the key points of her presentation. The IDMP dataset will fuse and grow in submission management. In the changing environment, there is a focus on shifting from document-based processes toward the management and evaluation of data while ensuring data continuity.



Vision of an integrated submission landscape

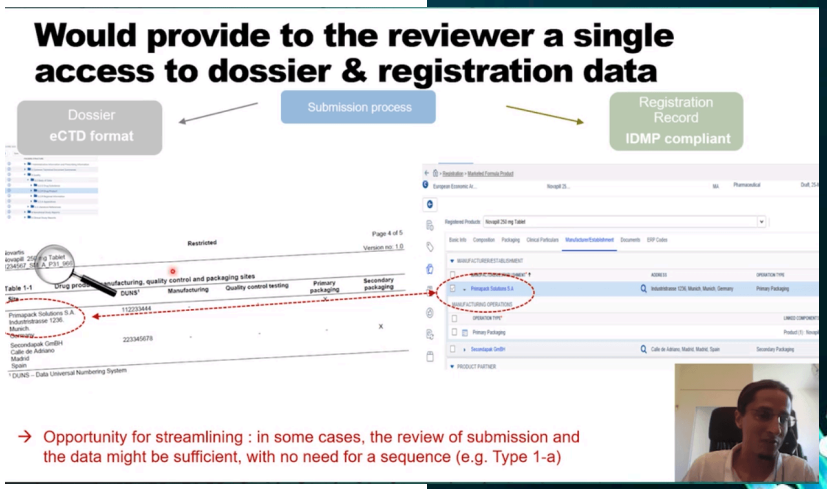
Laurent Lefebvre, Associate Director in Regulatory Affairs Global Drug Development CMC, Novartis

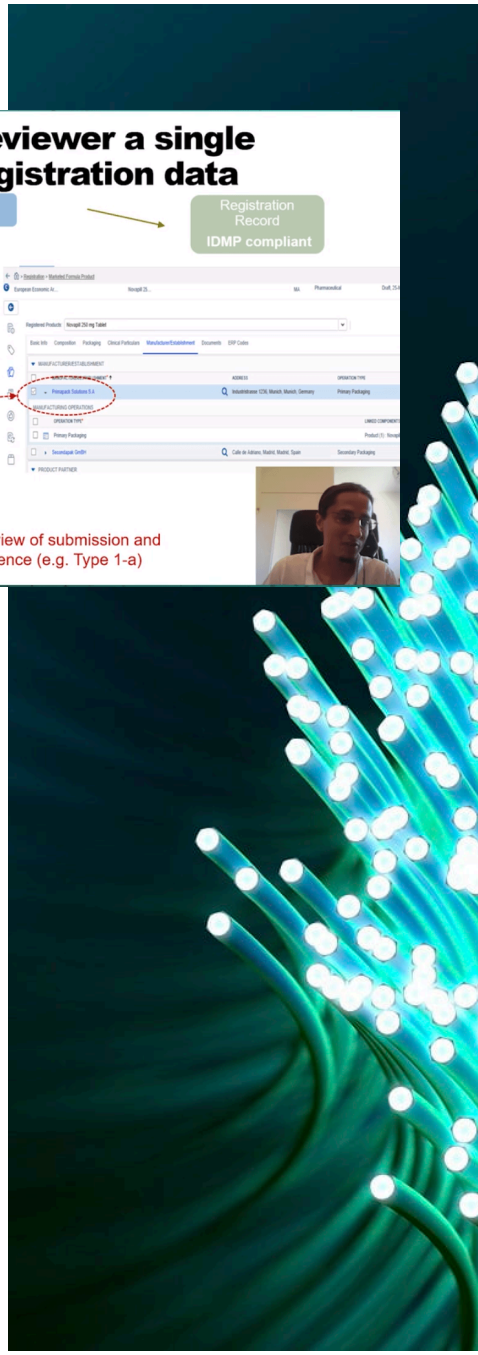
Laurent Lefebvre presented his vision of an integrated submission landscape. He first reviewed how the industry has progressively added data aspects to the document-exchange based regulatory approach in order to create a holistic regulatory information management system. He envisions the creation of this type of integrated system also on the HA side to facilitate submission, dossier, and data exchange.

Challenges encountered in the communication with HAs include the separate submission, dossier, and registration management. In contrast, the industry trend is to assemble all regulatory submission elements in a single place integrating all capabilities – a RIM system compliant with the IDMP format. Lefebvre then presented an existing industry RIM to illustrate the interconnectedness of the RIM elements. The vision aligned to the regulatory process will include an interactive exchange of questions and responses and the modification by each data owner of their information.

> "Lefebvre proposes to create a cloud-based EU RIM platform. It can connect the industry RIMs and a cloud-based EU HA RIM to share submission, dossier, and registration information."

The presented long-term vision for the IDMP landscape will fundamentally change the way information is exchanged and will streamline the business process. Lefebvre proposes to create a cloud-based EU RIM platform. It can connect the industry RIMS and a cloud-based EU HA RIM to share submission, dossier, and registration information. This would provide the reviewer a single access to dossier & registration data and streamline the process. Overall, this would create a dynamic review/approval process through direct messaging between RIMs.





Regulatory Information Management – IDMP, RIM systems, and building a database

Enhancing the overall efficiency of global Regulatory Information Management

Raj Srinivasan, Executive Business Partner, and Chikkam Ram Mohan Rao, Global Regulatory Business Partner, Navitas Life Sciences

This presentation focused on three main topics: challenges the industry faces with RIM management, optimisation of data handling across multiple regulatory systems, and process and data integration of end-to-end RIM.

Over the last decades, RIM has evolved from a paper process to digitalisation, exchange of documents, and finally exchange of data.

The driving forces behind this evolution are the harmonisation of data standards, collaboration among regulatory bodies, and the traceability and transparency of data.

A critical factor in this process is the change from application-centric to data-centric mindset to enable a single source of truth, alignment, and connectivity across all functional areas for transparency and accuracy. The data-centric approach considers data as a primary and permanent asset and builds a culture and architecture that puts data at the core of the organisation.

> "Data centricity is driven by the business, and an approximately 55% of all companies have started their journey to becoming data-centric."

The strategic, business value, and operational RIM priorities explore data centricity, progress the RIM culture, and implement RIM, respectively. Data centricity is driven by the business, and an approximately 55% of all companies have started their journey to becoming data-centric. The “5x5x5” approach for progressing the RIM culture was presented, which considers 5 dimensions (governance, process, culture, data, and technology) and 5 RIM maturity levels.

Regulatory affairs should support science and discovery, regulatory

information data provisioning, structured submissions, connectivity and interoperability, and life cycle management. A case study was presented for the establishment of an efficient RIM that improved data management and data quality, mitigated delays, ensured global alignment and transparency for timely change implementation, and resulted in zero post-approval compliance issues.

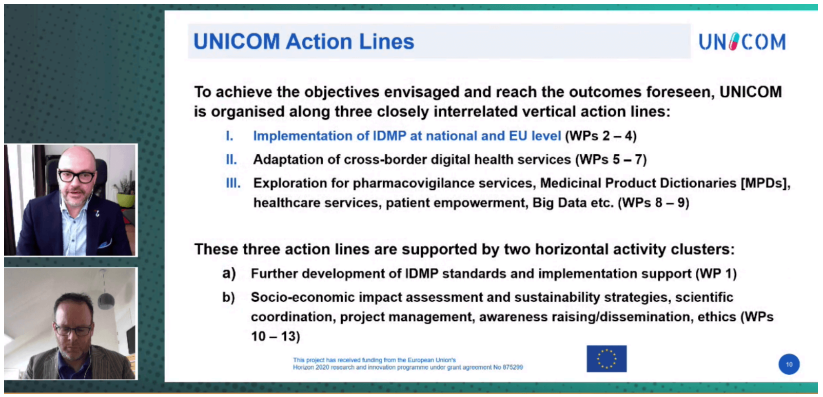
The RIM process flow includes internal and external stakeholders and has become more complex with the evolving regulatory requirements. Data handling across multiple regulatory systems should be facilitated to ensure an integration and optimisation of the process.

ISO IDMP related implementation at and by the regulator - MEDB experience and views on substance management

Joris Kampmeijer, CIO & Frits Stulp Project Manager EU-SRS, CBG-MEB Netherlands

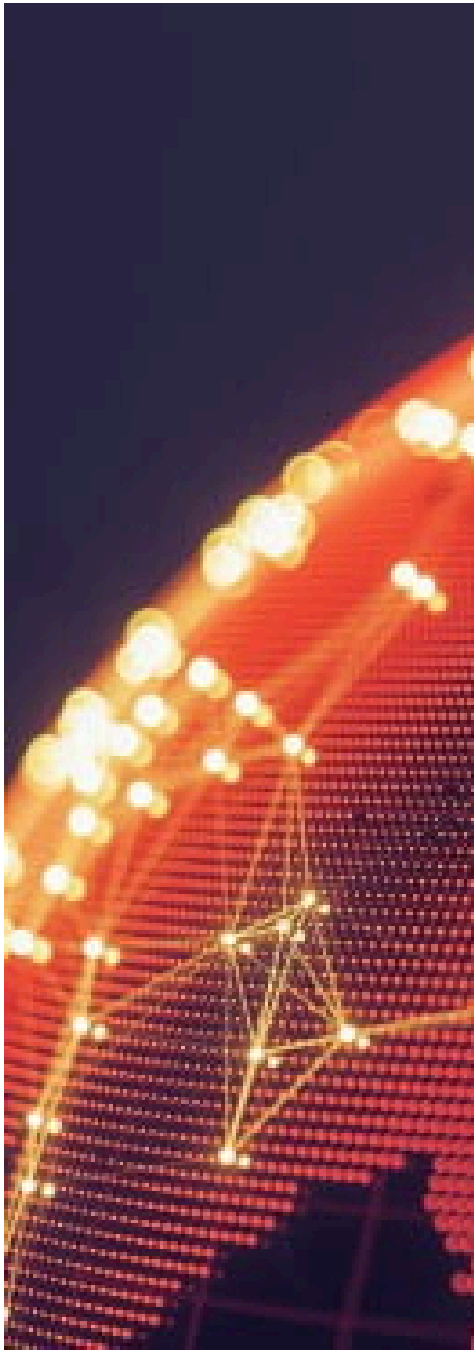
Substance management is a critical subject for regulators. An example is the identification of the possible human carcinogens nitrosamines in sartan medicines in 2018.

This led to a full review of the procedures for substance management, and further development of information technology systems (including for



substances) was recommended. In that regard, the European Substance Registration System (EU-SRS) is crucial to support substances (S), veterinary and human medicinal products (P), organisations (O), and referentials (R) (SPOR).

The scientifically sound EU-SRS system was originally developed by the FDA. It includes hierarchy and relationships between substances, references, codes and names, chemical structures, and search functions. The EU-SRS has been endorsed for implementation during 2020–2022. Moreover, it has been included in the Telematics Strategy & Roadmap and in the UNICOM project, which will focus on the conversion of key regulatory and clinical processes to use IDMP. By accelerating the diffusion of ISO IDMP standards,



> "The presenters reviewed the role of EU-SRS in SPOR and in reaching the ultimate goal: “to have one version of the truth”."

UNICOM supports regulatory processes, cross-border digital health services, global pharmacovigilance, and improved healthcare and medical research. Currently, a lot of effort is focused on the implementation and validation of the EU-SRS, which will be handed over to the EMA in 2022.

Next, the presenters reviewed the role of EU-SRS in SPOR and in reaching the ultimate goal: “to have one version of the truth”. To attain this goal, structured data and supporting documents should be submitted, the structured data should be assessed, and the approved data should be stored in an EU-database. However, this is not the current standard procedure, and a process is being developed to move from post-authorisation to pre-submission of structured data. The SPOR Task Force endorses a two-phase approach, building upon a centralised implementation first (EMA) and allowing the transition of NCAs to ISO IDMP over a period of time.

Current goals of the overall programme management of this part of the Telematics Roadmap include pre-registration of required master data to support various processes, product assessment and approval, signal management using coded data, clinical trial management, reporting of shortages, etc. This process is based on a common data repository of product information in Europe. Industry can also contribute by preparing IDMP/SPOR data on products, upgrading processes and systems where needed, contributing to the massive change in the joint way of working with HAs, and staying open and constructive.

Telematics Strategy in the EU

Vada A Perkins, Executive Director, Regulatory Policy & Intelligence/ Head, Regulatory Intelligence, Bayer

Vada Perkins reviewed the impact of telematics globally and specifically in the EU and highlighted certain perspectives regarding the international market. He began his presentation with the traditional definition of telematics, which is the long-distance transmission of computerised information. However, he stressed that the role of telematics has evolved with the data revolution in regulatory science, which has placed

high value on data integrity.

As a result, data governance, guiding principles, and data standards are being developed by international regulators and industry to ensure a transition to more efficient regulatory assessment. An example of quality standards implementation is the FDA cross-centre initiative for structured PQ/CMC submissions by the development of standardised data elements, terminologies and data structures, and the implementation of a data exchange standard for PQ/CMC data. This initiative has recently been internationally endorsed as a new topic for the ICH.

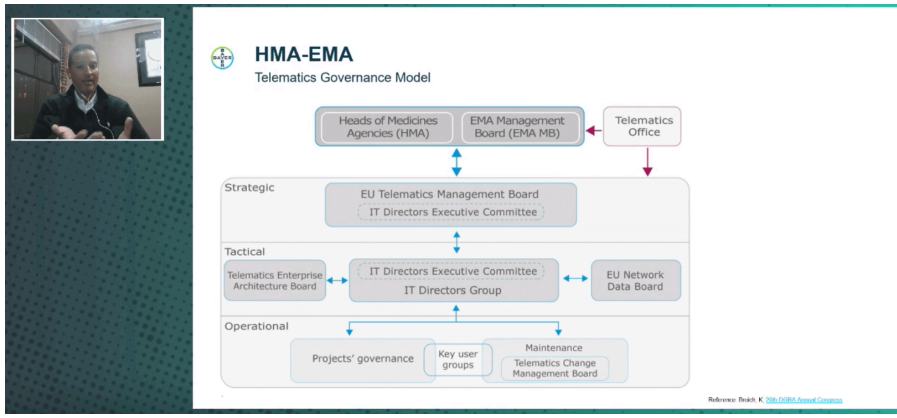
Next, Perkins presented the telematic governance model of the HMA-EMA. Its strategic efforts are being led by the EU Telematics Management Board. It includes several relevant programmes, such as eCollaboration, Pharmacovigilance, Clinical Trials, Data Integration, and Veterinary. The EU IDMP/SPOR Task Force Group falls under the Data Integration programme. However, the Extended Telematics Implementation Roadmap 2020–2021 also impacts a number of other programmes and standards.

> "The concept of telematics is evolving, and telematics is now being viewed as a horizontal activity to support a broad range of initiatives."

The EU HMA/EMA Joint Big Data Taskforce has provided 47 recommendations and prioritisation of future actions. The aim is to achieve evidence acceptability in support of the evaluation and supervision of medicines in nine key areas. Notably, two of these nine areas are data standardisation and data quality, which emphasises the pivotal role of data quality for data analytics.

The EU Telematics Strategy Concept Paper 2020–2025 sets the aims to streamline regulatory decision making through master data management, sharing/ exchange of assessment reports, and technical standards to facilitate automated data and document exchange and to reduce the administrative burden on data management.

Perkins stressed that the concept of telematics is evolving, and telematics is now being viewed as a horizontal activity to support a broad range of initiatives. He then illustrated how telematics is relevant to different focus areas of the European medicines regulatory network (EMRN)



Strategy 2025. Telematics is pertinent to the availability and accessibility of medicines (Focus Area 1) by matching supply data and demand data of medicinal products at a network level; reducing the barriers to national access or distribution via electronic public information, and increasing the transparency on the marketing status of centrally authorised medicines and the insight to what is marketed in neighbouring countries.

Telematics is also relevant to the strategic goals of Focus area 2, including digital health, real world data, data and process analytics, digital tools, and digital transformation. Telematics can contribute to innovation (Focus area 3) by providing digital tools and data standardisation and supporting innovation and digitalisation in clinical trials.

Notably, telematics is especially relevant to Focus area 6 (sustainability of the Network and operational

excellence) to drive regulatory optimisation, ensure that all NCAs contribute to Network operations, and combine and enrich EMRN internal data with external data sources.

Perkins also addressed the challenges associated with the telematics relevance to the EMRN Strategy 2025, including resource allocation and funding gaps, and strategies to overcome them. He concluded his presentation by emphasising the need to think holistically in redefining the role of telematics, taking into account the development of technology, IT, and regulatory sciences.

Following his presentation, Perkins answered several questions. Regarding the chances of Europe to be a leader in the digitalisation of the regulatory process, he emphasised that both cloud and dynamic regulatory assessment initiatives are currently being discussed in Europe and other areas and will be important for the advancement of the field. The challenges faced by small and medium enterprises in terms of digitalisation affordability were also addressed.

Perkins believes that accommodations are necessary for small and medium enterprises to ensure they can have access to digitalisation. Moreover, the involvement of multiple stakeholders from health authorities, industry, and data and technology companies in the process is important because it will make digitalisation more ubiquitous and bring down the cost.

The role of the industry in the Telematics Strategy implementation was discussed. Perkins believes that all stakeholders involved in the life cycle of data should be involved in the process, and the role of industry as a data generator is very important. Moreover, there will be a need for even broader cooperation between regulatory life sciences and healthcare. The role of the WHO as an important stakeholder in the process was also addressed.

Top panel discussion: Redesigning the regulatory landscape

Assessing the paradigm shift from today's standard way of working towards a data-driven future

Redesigning the regulatory landscape: Assessing the paradigm shift from today's standard way of working towards a data-driven future

One of the most popular sessions of the week examined the regulatory industry's progress towards data-driven ways of working.

Here we explore the highlights of the panel discussion, which featured:

- **Kim Brownrigg,** Senior Principal, Accenture
- **Rodrigo Palacios**, PTR Global Head for Business Systems, Roche
- **Vada A. Perkins,** Global Regulatory Policy & Intelligence, Bayer
- **Rebecca Brady**, Conference Producer, Informa Connect Life Sciences (Moderator)

First, the shift to data-driven regulatory environment was addressed. Rodrigo Palacios emphasised that, with the fast pace of innovation in the pharmaceutical industry, there is a need to retool the whole regulatory process to meet the new opportunities and demands.

Vada Perkins believes that in the past the value of data was understood, but the level of innovation and technology did not allow its full utilisation. However, current technology advancements are changing this situation, and training, processes, and harmonisation should come together for optimal data analysis.

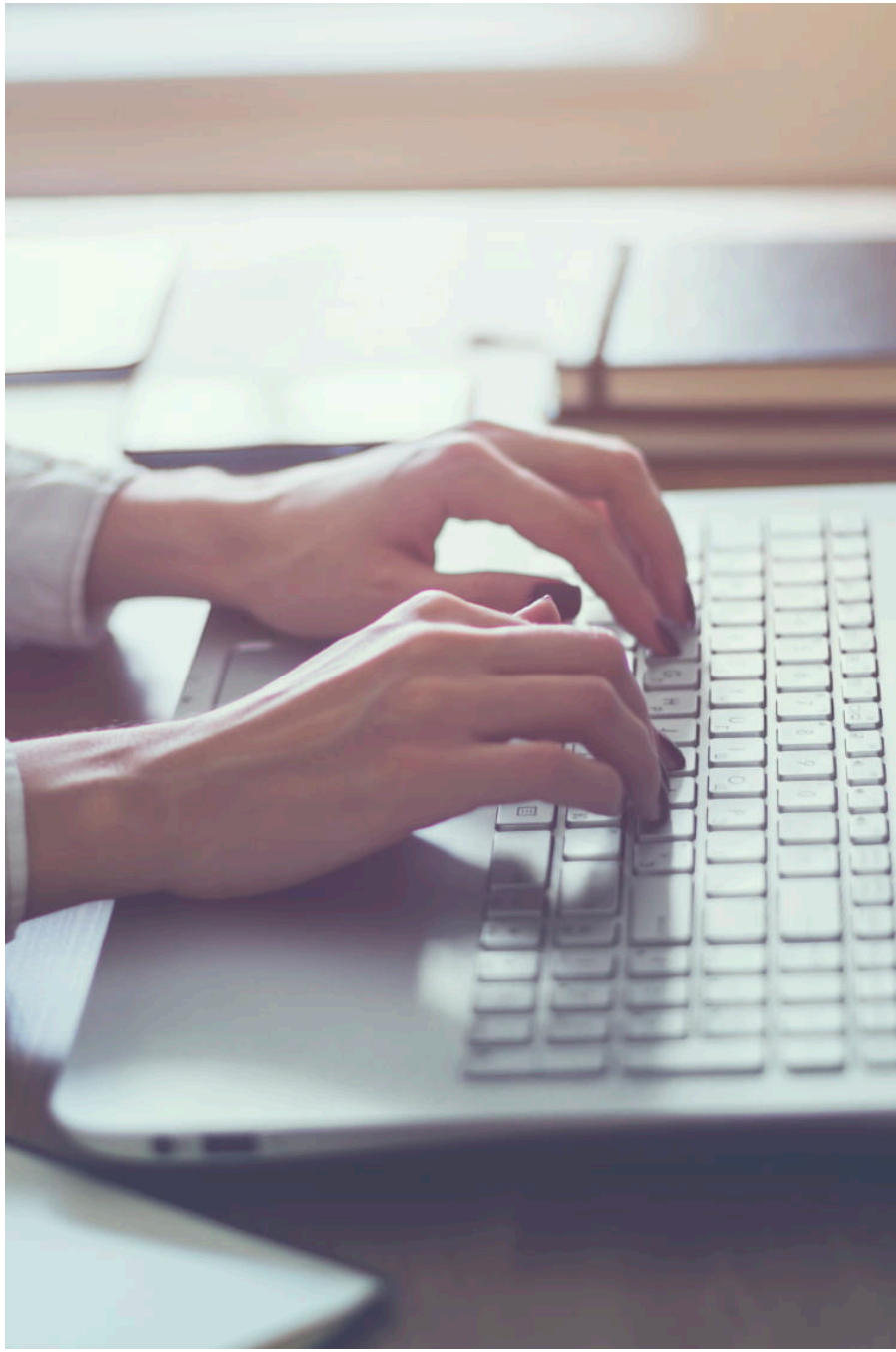
The experts were asked how the data-driven technology would have changed the current environment, including the COVID-19 pandemic, if it was already implemented. Vada Perkins stated that the possibility to access and summarise data in real time would have facilitated the decision-

making process, including therapeutic decisions. In the case of the COVID-19 pandemic, this would have allowed fast access to data on promising medicines, which would have facilitated their further development. Rodrigo Palacios indicated that the implementation of data-driven technology would have permitted even better harmonisation of the knowledge regarding medicine availability in different countries of the EU and mitigation of any potential drug shortages.

Kim Brownrigg commented on the value of data-driven approaches for businesses. She indicated that a data-driven approach would allow businesses to do more with their data, avoid data duplication, and gain further insight from them. Vada Perkins agreed with this position and explained that the repurposing of data would increase the efficiency also from the regulator's perspective. Rodrigo Palacios emphasised that avoiding data duplication would also streamline the process for patients, speed up the review process, and help face new challenges.

> "Data entry being accurate, consistent, of quality, structured, and standardised is vital for whatever possible readout … Just get the data itself correct."
>
> **Kim Brownrigg, Senior Principal, Accenture**

The possibilities and challenges in the implementation of the data-driven process were reviewed by Kim Brownrigg, who views the situation as an opportunity for business and IT to come together in the development of a holistic approach. The role of data governance analytics to drive innovation was also discussed. Kim Brownrigg emphasised the significance of a data management system to ensure high quality of the entered data



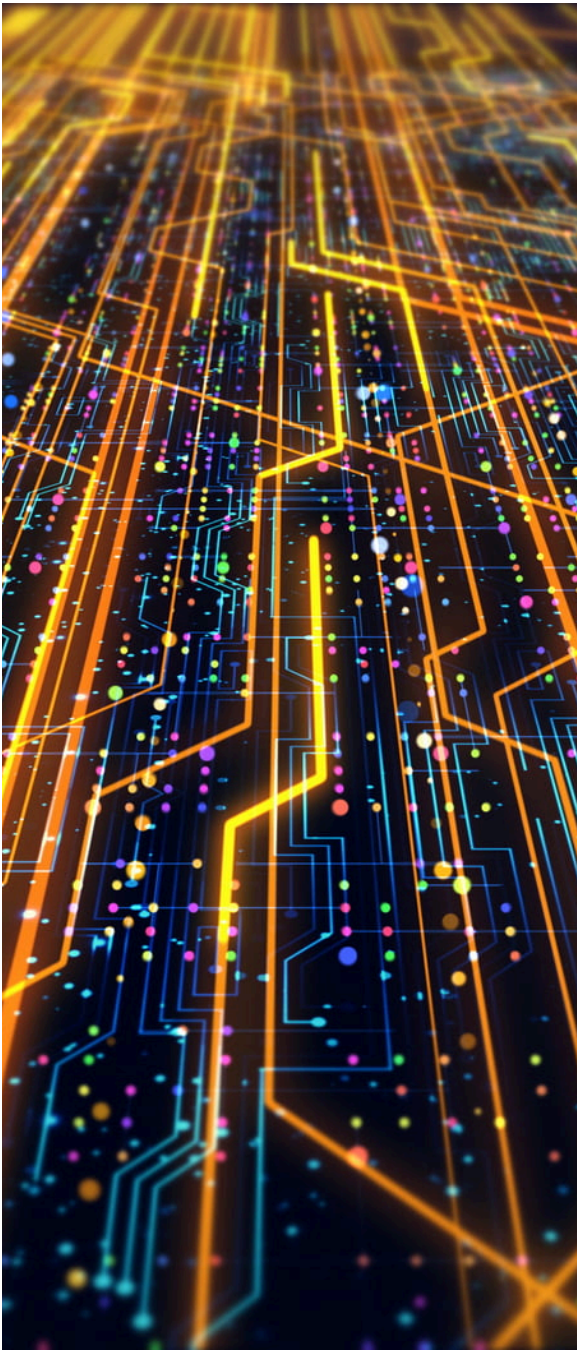
and thus to drive the correct output. Vada Perkins discussed the governance of real-world data and the importance of infrastructure implementation to ensure appropriate analysis.

Next, a strategy for the attainment of more reliable data from original sources was discussed. Rodrigo Palacios views the workforce culture as one of the challenges, and a lot of effort is invested in raising the workforce awareness. Vada Perkins emphasised the fact that the number of stakeholders in the field is increasing and also includes technology and data companies. Thus, cohesion among stakeholders is necessary. FDA PQ/CMC and new submission formats were also addressed. For Vada Perkins, this is an example of structuring complex information for more efficient review and for the development of analytics for a variety of purposes. Kim Brownrigg noted that, with time, data may also be produced in a more structured way by laboratories.

Finally, the challenges faced by smaller companies in the implementation of a data-driven approach were discussed. The panelists agreed that partnerships with technology companies, formation of consortia, and collaborations with health authorities will help deal with these challenges.

The participants concluded the discussion their key messages concerning data-driven RIM. Kim Brownrigg emphasised that “data entry being accurate, consistent, of quality, structured, and standardised is vital for whatever possible readout … Just get the data itself correct.” For Vada Perkins, a holistic approach involving collaborative work between the business, regulatory authorities, and IT specialists is required to be successful. Rodrigo Palacios highlighted the importance of strong external partnerships to achieve data-driven RIM, which is a must-have for both pharma and regulatory authorities.

Top Q&A Session: eCTD v4.0



Top Q&A Session: eCTD v4.0

The most popular Q&A session of the week discussed the introduction and implementation of eCTD v4.0. The panel featured:

- **Alastair Nixon**, Director, Submission Standards, Global Regulatory Platform and Delivery, GlaxoSmithKline
- **Dr Bernd Misselwitz**, Director, Regional Head of Regulatory Submission, Bayer
- **Rodrigo Palacios**, PTR Global Head for Business Systems, Roche

---

The experts started the session by discussing how the eCTD v4.0 will work if it becomes mandatory in 2025. Alastair Nixon believes that the eCTD v4.0 could work right away, but currently there is a lack of drive for its implementation. He views the eCTD v4.0 as an apparently better way to do submissions, and while 2025 is the timeframe for its mandatory implementation, he hopes to see pilots already next year. Dr Bernd Misselwitz raised the need for a clearer communication with regulators from a European viewpoint. He believes regulators should commit to a roadmap and milestones for the eCTD v4.0 implementation because this will clarify the need and timing for different tools.

Next, the future of the eCTD in view of the restructured data submission was discussed. Rodrigo Palacios believes the eCTD v4.0 may help transform pieces of the dossier into structured data. In the more distant future, he envisions a discussion to identify the most "fit for purpose" way to exchange data with regulators. The participants agreed that, since the eCTD requirements were developed in 2008, it is time to brainstorm for

ways to move forward, considering the new developments, including cloud technologies, reliance pathways, etc.

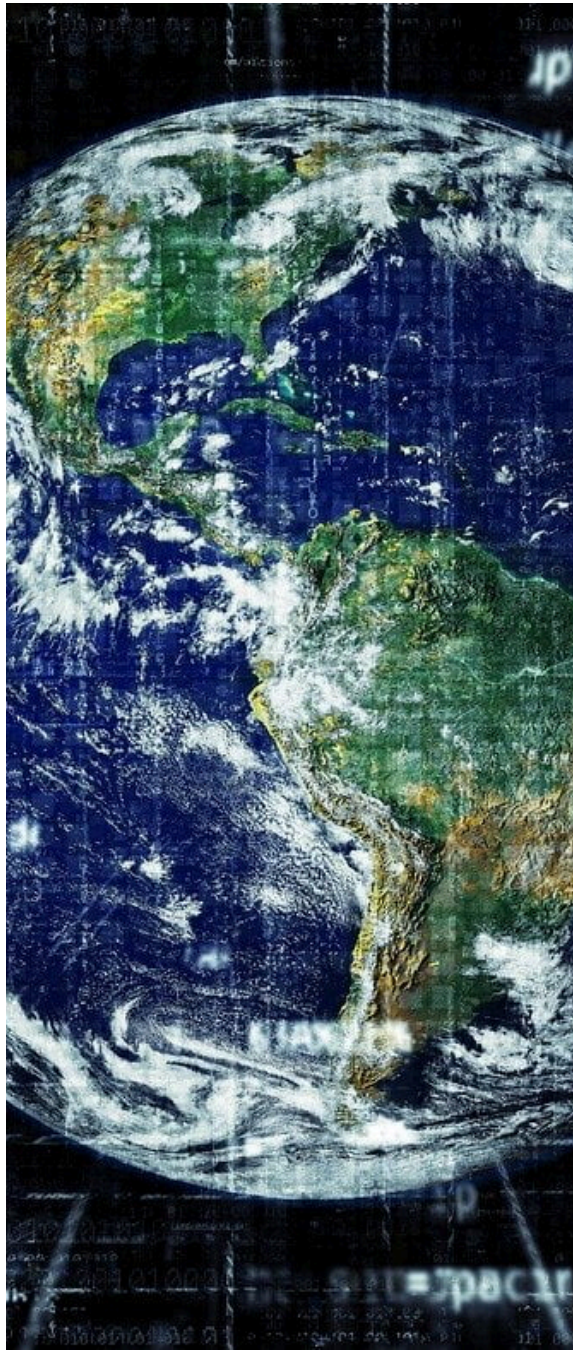
The experts discussed strategies to accelerate the global implementation of eCTD v4.0. Dr Misselwitz reiterated the need for clear timelines and tools for the eCTD v4.0 implementation. He also mentioned the chance to introduce the eCTD v4.0 into countries that are currently looking to move to electronic submission standards. Rodrigo Palacios stressed the importance of infrastructure, specifications and policies set up by regulators, and leveraging the power of new technologies to facilitate the global eCTD v4.0 implementation.

Alastair Nixon emphasised the need for a drive in countries using the eCTD format to move toward eCTD v4.0. This may also be a motivator for countries looking to newly develop an electronic submission system to join the eCTD format instead of developing an alternative electronic submission system.

Another topic of discussion was how to optimise eCTD data management. Rodrigo Palacios emphasised the need for strong data management in companies. For example, Roche works to raise employees' awareness of data management by introducing the "data citizenship" initiative. There is a need to start a knowledge journey in order to update and automate practices and technology to track the data from origin to submission.

The experts concluded the session with their final takeaways. Alastair Nixon emphasised the need for a more specific milestone European Union roadmap for eCTD v4.0 implementation. Rodrigo Palacios believes that a strategic view is needed in order to take advantage of the features of the eCTD v4.0 standard: two-way communication, granularity, and ability to reuse and update documents across applications.

The guidelines and policies of the regulator and the end-to-end process should be looked at to make the process more efficient. Since the implementation of this very new standard will require a lot of time and effort to implement, its benefits should be utilised. Dr Misselwitz explained that better communication and promotion of the eCTD 4.0 is needed, including by the EMA. In parallel, alternative standards should be looked at for the future.



Hot Topic Discussion: Brazil Focused Q&A

Hot Topic Discussion: Brazil Focused Q&A

During the week, the processes of many global regulatory bodies were discussed. This session answered burning questions surrounding the Brazilian Health Surveillance Agency (ANVISA) and its latest regulatory changes and ongoing challenges.

The panel featured:

- **Dr Patricia Kott Tomazett**, Health Regulation Specialist, General Management of Drugs, GGMED, ANVISA
- **Dr Thomas Kirchlechner**, Director Regulatory Policy Biosimilars, Sandoz GmbH
- **Darius-Jean Namdjou**, Global Regulatory Strategist, Grünenthal GmbH, Germany (Moderator)

First, Dr Patricia Tomazett provided an update on the status of eCTD v4.0 adoption by ANVISA. The adopted version will definitely be 4.0, and currently the agency is working on the implementation of a number of technical aspects.

Dr Thomas Kirchlechner answered a question on the debate about the interchangeability between biosimilars and the perceived lack of a harmonised approach between regions. He believes that there are misconceptions about the interchangeability requirements, with an expectation for stricter interchangeability requirements in the USA, which is not the case. Notably, many countries that have not developed their own requirements follow the requirements of the World Health Organisation (WHO).

The next question concerned the harmonisation of regulations in light of the COVID-19 pandemic. Dr Tomazett explained that ANVISA wants to keep an open channel for

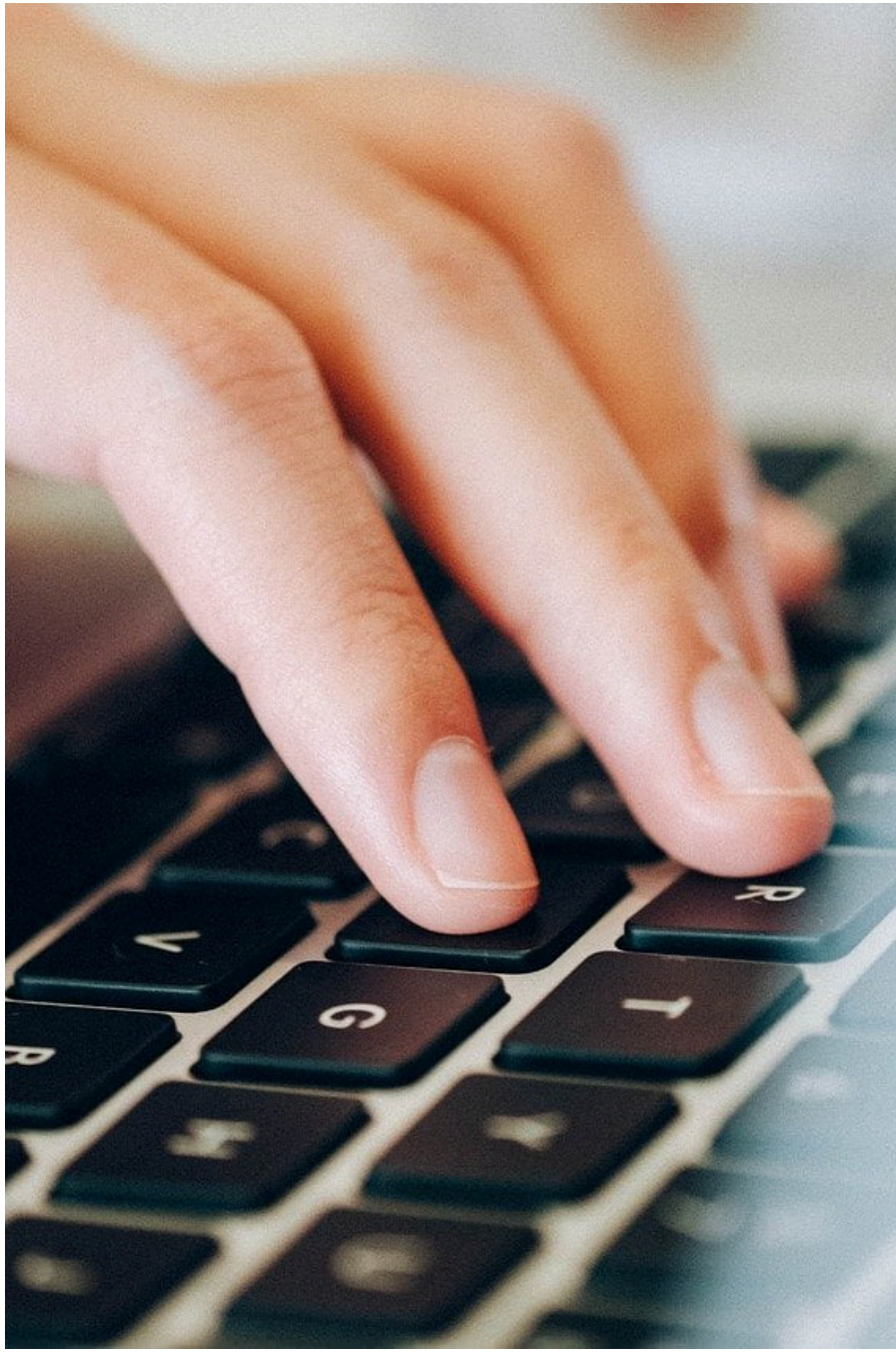
communication with the industry to help streamline the harmonisation process. It is important to follow the national guidelines related to ICH regulations, and to discuss any potential difficulties a company may face in the implementation of the ICH guidelines adopted by ANVISA.

Several questions focused on specific ANVISA regulatory processes. One question addressed the requirement for local studies for generic drugs in Brazil. Dr Tomazett explained that there are specific requirements regarding bioequivalence and clinical studies for generics.

> "The bioequivalence study centre has to be certified by ANVISA but does not need to be located in Brazil."

The bioequivalence study centre has to be certified by ANVISA but does not need to be located in Brazil. There are also certain requirements regarding the report completeness and data quality for clinical trials for generics; however, it is not necessary to conduct the clinical study in Brazil or on Brazilian subjects.

Next, the timelines and steps for orphan drug registration in Brazil were discussed. Dr Tomazett explained that a pre-submission meeting is mandatory to review the documents for orphan drug registration, followed by a 60 days review procedure and the exchange of questions

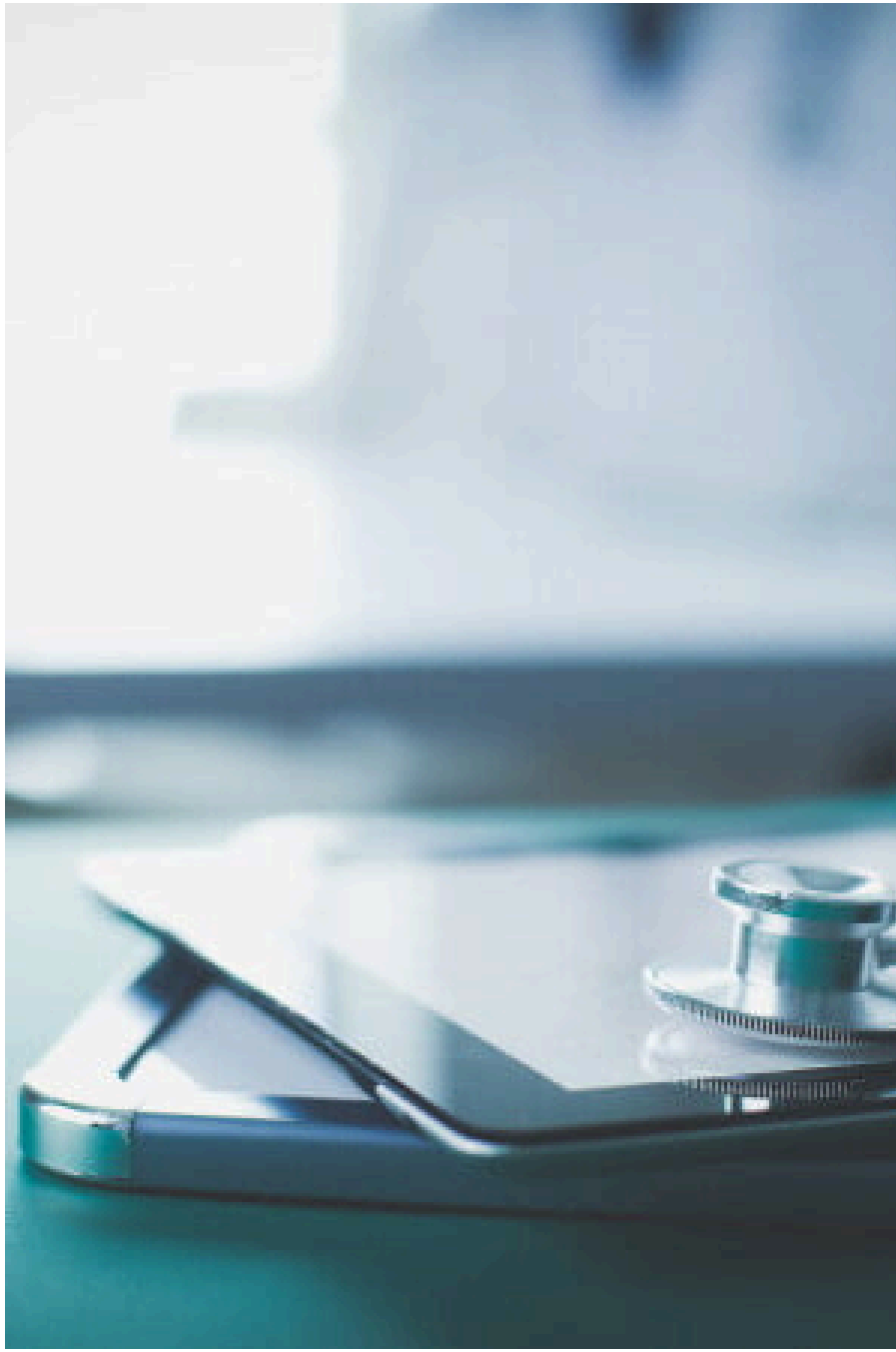


and additional information. With regard to the recent variation stability guidelines for biologics in Brazil, Dr Tomazett clarified that there will be a transitional period.

> "A dialogue with ANVISA should be initiated promptly to ensure compliance with Brazil-specific requirements"

Dr Kirchlechner shared key learnings from his experience with the approval of biosimilars in Brazil. He pointed out that transport validation should be planned early on, and that a dialogue with ANVISA should be initiated promptly to ensure compliance with Brazil-specific requirements. Moreover, he believes that the new eCTD format will facilitate the process. His advice to new companies trying to register a drug in Brazil is to do a thorough market research for an existing product development partnership (PDP). If there is one, it may not make sense to develop a second molecule. If no PDP exists for the molecule of interest, it may be reasonable to enter in a PDP and to introduce technology in Brazil, which will give the company an advantage with the market share.

The final questions again focused on ANVISA regulatory processes. Dr Tomazett explained that the new API regulation in Brazil implements many ICH guidelines and will have a transitional period until next year. Regarding the inspection of global manufacturing sites by ANVISA, Dr Tomazett explained that ANVISA has applied for a PIC/S certification. Until a positive result on the PIC/S certification is achieved, ANVISA will continue to inspect global sites. When a PIC/S certification is acquired in the future, ANVISA will be able to accept the reports of local authorities.



We hope to see you at Global Pharmaceutical Regulatory Affairs Summit 2021!

informaconnect.com/global-pharmaceutical-regulatory-affairs