EU NTC 10-year anniversary event

Event report
30 May 2024

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

Introduction

In 2024, the EU Network Training Centre (EU NTC), a joint EMA-HMA initiative, celebrated its 10-year anniversary. Over the past decade, the EU NTC has provided high-quality scientific and regulatory training within the European Medicines Regulatory Network (EMRN), ensuring that staff across the Network are equipped with the skills and knowledge needed to navigate the regulatory complexities of the life sciences and pharmaceutical sectors.

The event highlighted past successes and outlined future plans to continue building capacity and capability across the EU for better patient and animal health outcomes. International partners and other stakeholder groups also shared their experiences with similar networks, contributing valuable perspectives.

The EU Network Training Centre: 10 years in operation

Key messages

- The EU NTC is a model for collaboration and training for regulators across Europe, supporting the availability of high quality, safe, and effective medicines for all patients.
- To uphold the current level of medicines regulation in Europe in the years to come, work sharing between NCAs is crucial.
- Regular review and updating of acquired skills is essential.
- Assessment capacity should be increased by integrating external expertise. We could explore the use of an untapped pool of resources such as students, academics as well as retired staff.
- Close collaboration between EU NTC and initiatives aiming at increasing regulatory/scientific capacity and capability, such as IncreaseNET, is key to ensure sustainability.

Mission and vision of the EU NTC around regulatory, scientific and digital topics

The EU NTC's mission is to promote and ensure that good scientific and regulatory practices are shared across the EMRN along with harmonised training standards, through the provision of high quality and relevant training shared through a European central platform: the EU NTC Learning Management System (LMS).

Key achievements over the last 10 years include the implementation of the Learning Management System, the creation of the L&D toolkit, the launch of the EU NTC portal, a refreshed and modern-looking newsletter, and the expansion of the training catalogue to cover digital skills under the umbrella of the Digital Academy.

Looking forward, the EU NTC aims to be a key contributor in capacity and capability building within the Network while also positioning itself as a thought-leader in fostering trust in the EU regulatory system and collaborating globally to support world-wide regulatory excellence.

More concretely, the EU NTC will expand its reach to new audiences (such as patients, healthcare professional representatives, and international regulators…), develop more specialised programmes under the Digital Academy,

explore innovative approaches to training development and delivery and continue enhancing the quality and accessibility of training materials with course developers.

Benefits of EU NTC for NCAs and the EU Regulatory Network

A balanced and strong European medicines regulatory network is crucial for public health in Europe. To maintain the current level of medicines regulation in the coming years, it is vital to invest in regulatory capacity building across Europe.

Aimad Torqui, Head of Division at MEB (Medicines Evaluation Board, The Netherlands) and María Jesús Lamas, Head of AEMPS (Spanish Agency for Medicines and Health Products, Spain) presented how their National Competent Authorities make use of the EU NTC as part of the training programmes to onboard and upskill their staff members.

The EU NTC can address knowledge gaps in areas such as the interface between medicines and medical devices, parallel scientific advice (regulators' and HTAs'), digital competencies, GMP inspections… It is also essential to complement theoretical training with practical, hands-on programs in critical areas.

EU Scientific Committee's vision for training in a changing EU environment

The EU NTC has played a crucial role in uniting NCAs and enhancing their capabilities in medicines evaluation. Moving forward, there is a need to mobilise external expertise for regulatory assessment and scientific advice. Encouraging academic contributions and lectures within the EU NTC framework could also enhance training quality and relevance.

EU4Health Joint Actions on capacity building in the EU

IncreaseNET is an EU4 Health Joint Action, co-funded by the European Union and led by the JAZMP (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia), which aims to support the capacity and competence building of the EU medicines regulatory network. Running from January 2024 to December 2026, the project involves 27 EU/EEA Member States and Ukraine. Its primary objective is to provide a framework for increasing the necessary regulatory expertise and competences within the EMRN, developing additional capacities and enhancing existing ones by focusing on the efficient use of resources.

IncreaseNET is working very closely with the EU NTC to ensure that its deliverables are sustainable post-project.

Views of key stakeholders

Key messages

- Continuous training is needed in the area of patient engagement.
- Early & regular dialogue, early cooperation and mutual exchange are key elements in the collaboration between regulators and healthcare professionals.
- Training is not only about building organisational and personal capabilities but also about building alignment around common goals to create professional, strong and capable networks.

Expectations from patient representatives on the role of training in supporting the life science sector

As the NTC enters the next phase of its journey, patient representatives welcome the focus on increased collaboration with stakeholders. They encourage the EU NTC to seek the experience and expertise of patient organisations to ensure that the content that is made available to patients and patient experts addresses their needs. Additionally, they support increased training on patient engagement for regulators to ensure the value of patient involvement is recognised and further leveraged at all levels.

The next few years will offer great opportunities to step up patient engagement in the regulatory decision-making process. The proposed inclusion of four patient representatives and four alternates at the CHMP under the revised pharmaceutical legislation shows how much progress has been made – while emphasising the need to retain the expertise of patients currently engaged in EMA committees. However, patients' meaningful contribution cannot happen without adequate compensation, resources and training. For the next 10 years, patient representatives look forward to working together with the EU NTC to fill the knowledge gap.

Synergizing regulatory and academic forces: advancing training and learning in the life sciences sector

Leveraging the synergies between regulators and healthcare professionals is key to advance public health and innovation. The key elements of such collaboration are early & regular dialogue, early cooperation and mutual exchange. For healthcare professionals to be able to provide meaningful and valuable input into regulatory processes, training is essential.

The European Medicines Agency has been involving healthcare professionals in their core work, for instance through the representation at advisory groups and working parties, ad-hoc discussions and multistakeholder initiatives, etc. since its creation in 1995. Over the past 10 years, such collaboration has become more structured under a formal framework for interaction, which has led to increased trust and bidirectional dialogue. Building on this positive experience, such framework could be expanded to interact with other external stakeholders such as academia, which will bring benefits to both parties by bringing together the latest and most innovative scientific knowledge with regulatory expertise.

Navigating tomorrow: insights on horizon scanning and public-private collaborative support strategies

The Innovative Health Initiative (IHI) is a public-private partnership for health research and innovation, funded primarily by the EU and the health industries in Europe. It aims to deliver safe and effective health innovations, particularly in areas where there is an unmet public health need.

Regulatory science is a pivotal part of IHI, as shown by the fact that a large proportion of IHI projects include regulatory endpoints. Training is therefore key to ensure stakeholders involved in IHI projects initiate early dialogue with the relevant regulators as it is critical for success. But training is not only about building organisational and personal capabilities. Given the multinational and multi-stakeholder environment in which the health sector operates, it is also about building alignment around common goals to create professional, strong and capable networks.

IHI holds regular regulatory science summits aiming at providing a forum for open and constructive discussion on regulatory science challenges and opportunities between a wide range of interlocutors including EMA and the chairs of its scientific committees, the European Commission, medical device regulators, FDA, health technology assessment bodies, and representatives from industry associations. The following 5 topics came out of the last IHI regulatory summit: Rare Diseases, Paediatrics, Artificial Intelligence, Real World Data and Regulatory Sandbox, which can be topics for future training courses within the EU NTC.

Training in the wider landscape

Key messages

- Learning and skills development is a lifelong journey.
- Hands-on learning is a powerful tool for assessors as it enables them to better understand the dossiers under evaluation.
- Global harmonisation in the area of training and qualification of inspectors is key for mutual reliance.
- Coordination, harmonisation and alignment are key to achieve a single set of standards across the African continent.

Sharing US FDA's experience on training activities

Training is a key pillar of US FDA and as such, significant energy and resources are devoted to it. FDA training programmes are based on FDA's organisational structure, with each Centre having their own training programme specific to their area of expertise.

Not only does FDA offer training to their employees but they also have external-facing training geared towards the public and industry. This includes 'FDA 101' which provides an overview of how FDA works and is updated on a yearly basis.

In terms of internal FDA training, this covers technical, leadership, language and soft skills. Furthermore, this offer is complemented by 'experiential learning' programmes. This covers on-the-job training/mentoring, site visit training programs where FDA partners up with industry so that they open up their facilities in a non-inspectional setting, allowing FDA staff to observe manufacturing/testing operations for 1-2 days and hands-on training provided by research laboratories offering access to emerging and innovative technologies.

FDA provides joint training in partnership with regulators across the globe. An example of such partnership is a EMA-FDA pilot programme where both agencies exchange training in areas of particular interest. Such pilot could form the basis for strengthening EU-US collaboration in capacity and capability building.

Training activities beyond EU and global collaboration

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. Currently, there are 56 PIC/S participating authorities from all around the world.

PIC/S collects learning needs through regular surveys as well as through PIC/S sub-committees on Training (SCT) and on Expert Circles (SCEC). SCEC identifies areas for which new training should be organised whereas SCT is in charge of defining how training materials would be developed.

Training materials are developed by inspectors for inspectors. To facilitate inspectors' access to training, PIC/S has developed PIA (PIC/S Inspectorates' Academy), a web-based educational centre aiming at harmonising and standardising GMP training at an international level.

Cooperation between PIC/S and EU NTC is key to avoid duplication of efforts. One area that could be explored is the development of training covering assessors and inspectors (e.g. ICH Q12 – lifecycle management). Another area could be the development of a qualification process for assessors, similar to the one that currently exists for inspectors.

Lifelong learning for global health: the WHO Academy

Training has been highlighted as a top priority by WHO Member States, which has led to the creation of the WHO Academy. Its mission is to build a lifelong learning ecosystem that enables health and care workers, policymakers and WHO staff develop their capabilities.

WHO Academy has approximately 50 courses under development. These will be available through a digital platform to which access is restricted to specific target audiences in particular countries. The WHO Academy collaborates with experts in the technical teams at WHO headquarters to develop learning content. Such content is organised into 16 thematic priorities. WHO uses a five-step capacity building model for National Regulatory Authorities and has developed a global benchmarking tool to assess the capacities of agencies and guide the development of training programmes.

Establishing partnerships is at the heart of the work of the WHO Academy so moving forward, it will be important to develop linkages with institutions globally, including EU NTC, to enhance access to quality training. More specifically, WHO Academy and EU NTC could explore facilitating access to their respective training courses, co-developing training courses, sharing best practices and experience in learning, strengthening coordination in identifying and addressing Member States needs and building capacities for regulatory agencies in WHO Member States.

African Medicines Agency: EU-Africa collaboration

The journey of harmonisation and regulatory systems strengthening in Africa started back in 2005 with a vision to improve the access to medical products for the African continent. More recently, in 2021, the treaty establishing an African Medicines Agency (AMA) entered into force. AMA would be a supranational agency focusing on complex medicinal products that have been identified as priorities at continental level.

In order to overcome the various challenges identified to create AMA, it was clear that coordination, harmonisation and alignment were key to have a single set of requirements across the African continent. The African Medicines Regulatory Harmonization (AMRH) programme has focused on this area, which has resulted in the harmonisation of standards, guidelines and processes in 5 regional economic communities. In addition to establishing national partnerships, the AMRH has established global partnerships, for instance, with the European Medicines Agency to provide the necessary support to the operationalisation of AMA given the nearly 30 years of experience that EMA has in the coordination of the European Medicines Regulatory Network (EMRN). The strong partnership that has been established with the EU is now focusing on prioritising the enablers for a successful AMA and learning from the EU Network model.

As a continent, Africa needs a systematic way to build capacity. To this end, the work of the EU NTC can be leveraged to develop the necessary training frameworks.

Looking to the future – working collaboratively to address future scientific and technological challenges

Key messages

- Learning how to navigate the medicine regulatory system is essential to overcoming some of the barriers hampering the regulatory approval of novel products and treatments developed by Academia.
- LLMs are AI systems that have an increasing number of use cases in the healthcare regulatory environment. Moving forward, it will be key for regulators and healthcare professionals to establish partnerships with IT and AI specialists so that the potential of AI can be fully exploited to the advantage of patients and healthcare systems.
- Moving forward, the area where we will see a large amount of use cases for regulatory and compliance training is immersive learning.

Advancing healthcare excellence: sharing of best practices and scientific progress from a healthcare professional perspective

The main challenge that academic societies such as the European Academy of Allergy and Clinical Immunology (EAACI) encounter is overcoming the barriers hampering the translational development of novel products/new treatments developed by Academia. To address this challenge, it is key to learn how to navigate the medicine regulatory system. In this respect, a harmonised curriculum accessible to relevant scientific professionals throughout Europe would be extremely beneficial. It is also important for regulators to provide guidance to Academia on how to design successful drug-development programmes or other interventions and to create a culture of continuous learning about upcoming innovative therapies through knowledge exchange with academia. It is equally relevant to have timely alignment of regulatory requirements with evolving scientific developments and to explore the possibility of working together in the co-development of guidelines and requirements.

Opportunities for AI-enabled regulation: thinking the unthinkable

In November 2022, access to a large language model (LLM), Chat GPT, was provided to the general public. LLMs can be seen as 'language calculators', which increase human capacity to understand complex documents and process large volumes of information and generate human language text. LLMs are AI (Artificial Intelligence) systems that have an increasing number of use cases in the healthcare sector in general, and in the healthcare regulatory environment, in particular. Some of these use cases include the identification of errors and inconsistencies in documents for external publication, the creation of drafts based on different sources of information and the collection of patient experience data. Moving forward, it will be key for regulators and healthcare professionals to establish partnerships with IT and AI specialists so that the potential of AI can be fully exploited to the advantage of patients and healthcare systems.

New trends and innovation in training development & delivery

We are going through a profound disruption in learning & development nowadays as a result of generative AI, which will lead to training being more and more personalised in terms of learning pathways, languages, accessibility and most importantly, in terms of feedback.

Within the next year or so, we will not become designers of training materials but designers of context (scenarios, situations…) since large language models such as ChatGPT do not necessarily provide that context.

Moving forward, the area where we will see a large amount of use cases for regulatory and compliance training is immersive learning where immersive technology such as virtual reality and augmented reality is used to create simulations for students to e.g. practice skills. With immersive learning, a huge amount of data is generated, not only in terms of what the students are doing but also in terms of how they are behaving. This has significant benefits in terms of being able to provide highly personalised feedback, to assess skills and assess to what extent students are changing behaviours as a result of the learning experience.

Conclusion

The 10-year anniversary of the EU NTC proved to be an enriching and insightful event with diverse and inspiring perspectives from high-level speakers representing a wide range of stakeholders.

Going forward, we want to move towards version 3.0 of the EU NTC and for that, we have a strong foundation to build upon over the next decade to continue developing content and transferrable skills. There are opportunities for us to professionalise our training curricula, expand to new target audience and experiment with new digital tools in the development of innovative learning experiences.

Co-chairs and Moderators

- **Zaide Frias**, Head of Digital Business Transformation, EMA
- **Lars Bo Nielsen**, Head of Danish Medicines Agency (DKMA), Denmark
- **Lorraine Nolan**, Head of Health Products Regulatory Authority (HPRA), Ireland and Chair of EMA Management Board
- **Steffen Thirstrup**, Chief Medical Officer, EMA
- **Christa Wirthumer Hoche**, former EU NTC co-chair
- **Marko Korenjak**, Chair of Patients' and Consumers' Working Party (PCWP)
- **Melanie Carr**, Head of Stakeholders and Communication, EMA
- **Martin Harvey Allchurch**, Head of International Affairs, EMA

Speakers

- **Emer Cooke**, Executive Director, EMA
- **Rui Santos Ivo**, Head of National Authority of Medicines and Health Products (Infarmed), Portugal and Co-chair of EMA/HMA MAWP
- **Momir Radulovic**, Head of Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), Slovenia
- **Maria Jesus Lamas**, Head of Spanish Agency for Medicines and Health Products (AEMPS), Spain
- **Aimad Torqui**, Head of Division, Medicines Evaluation Board (MEB), The Netherlands
- **Harald Enzmann**, Chair of Committee for Medicinal Products for Human Use (CHMP), Federal Institute for Drugs and Medical Devices (BfArM), Germany
- **Sheila Kennedy**, EU NTC senior specialist, EMA
- **Esther Martinez**, EU NTC team lead, EMA
- **Marco Greco**, EMA Management Board patients' organisation representative, European Patients Forum
- **Rosa Giuliani**, Chair of Healthcare Professionals' Working Party (HCPWP)
- **Niklas Blomberg**, Executive Director of Innovative Health Initiative (IHI)
- **Katherine Tyner**, US FDA liaison officer to EMA
- **Jacques Morenas**, Chair of the PIC/S Committee of Officials and special advisor for the Inspection Division at National Agency for the Safety of Medicine and Health Products (ANSM), France
- **David Atchoarena**, Executive Director of WHO Academy, World Health Organisation (WHO)
- **Chimwewe Chamdimba**, Head of African Medicines Regulatory Harmonization Initiative at the African Union Development Agency, AUDA-NEPAD
- **Ioana Agache**, Past President of the European Academy of Allergy and Clinical Immunology (EAACI), Transylvania University of Brasov
- **Julian Isla**, Data and Artificial Intelligence Resource Manager at Microsoft and Member of Committee for Orphan Medicinal Products (COMP)
- **John Kilroy**, CEO of the Digital Learning Institute

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question www.ema.europa.eu/contact

www.ema.europa.eu

EU NTC 10-year anniversary event: report

EMA/424445/2024