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Global Regulatory Developments on Product Safety of Medical Devices

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January 2022

1. Introduction

The medical device regulatory landscape is continuing to evolve, and staying on top of changing legislation can be challenging for manufacturers of medical devices.

This whitepaper provides a list of key global regulatory developments from August 2021 to January 2022 in relation to product safety of medical devices. It aims to provide you with the latest regulatory information to help your business better respond to changing regulations and ensure compliance for your products.

It covers:

- Medical device framework regulations
- Product classifications
- Certification and registration of medical devices

2. Medical Device Framework Regulations

2.1. EU

(i) EU Commission Published Rules for the Application of Regulation (EU) 2017/745 in Relation to European Database on Medical Devices

This regulation sets out the modes of access to Eudamed via the restricted website for authorized users, and public websites for non-identified users. It provides requirements and procedures for registration in Eudamed and access to Eudamed via the restricted website.

Earlier in September 2021, the EU Commission published a guide to using EUDAMED - actor registration module for economic operators - Version 2.0, which provides more detailed information on how to use the system.

(ii) EU Commission Proposed to Extend Transitional Periods for Certain Devices and Deferred Application of Requirements for in-house Devices

The proposal aims to extend the existing transitional period for devices covered by a certificate issued under Directive 98/79/EC and to introduce tailored transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time under Regulation (EU) 2017/746.

The Commission also proposes to introduce a transitional period for the requirements for devices manufactured and used within the same health institution ('in-house devices'). This

will give health institutions extra time to comply with the new requirements and ensure that in-house tests, which are often essential –especially for rare diseases, can continue to be developed in clinical laboratories.

Devices with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this article may be placed on the market or put into service until 26 May 2025.

Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that directive and for which the conformity assessment procedure pursuant to this regulation requires the involvement of a notified body, may be placed on the market or put into service until the following dates:

A. 26 May 2025 for class D devices
B. 26 May 2026 for class C devices
C. 26 May 2027 for class B devices
D. 26 May 2027 for class A devices placed on the market in sterile condition

(iii) EU Commission Amending Harmonized Standards for Certain Medical Devices

On 4 January 2022, the EU Commission published Decision (EU) 2022/6 amending Implementing Decision (EU) 2021/1182 as regards harmonized standards for the following:

- Biological evaluation of medical devices
- Sterilization of healthcare products
- Aseptic processing of healthcare products
- Quality management systems
- Symbols to be used with information to be supplied by the manufacturer
- Processing of healthcare products and home light therapy equipment

On 7 January 2022, the EU Commission published Decision (EU) 2022/15 amending Implementing Decision (EU) 2021/1195 with regards to harmonized standards for the following:

- Sterilization of healthcare products
- Aseptic processing of health care products
- Quality management systems
- Symbols to be used with information to be supplied by the manufacturer
- Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

(iv) EU Medical Device Coordination Group Published Guidance Document on Application of MDR Requirements to Legacy Devices and to Devices Placed on the Market Prior to 26 May 2021

As per Medical Device Regulation 2017/745 (MDR), certain devices certified under the prior Medical Device Directives 93/42/EEC or 90/385/EEC may, for a transitional period, continue to be placed on the market after the date of application of the MDR on 26 May 2021 without being certified under MDR, provided that the MDR rules regarding surveillance and vigilance be complied with. This document provides guidance on this issue, particularly to what extent periodic safety update reports (PSURs) must be created and submitted.

2.2. UK

(i) UK Published Guidance Document on Regulating Medical Devices

The Medicines and Healthcare products Regulatory Agency (MHRA) published updated guidance on medical devices regulation in the UK on 1 January 2022, which was updated to reflect changes to medical device regulatory requirements that will take effect on 1 January 2022.

This guidance document provides information on the UK system, including for getting your device certified, conformity marking your device and registering your device with the MHRA.

This guidance document contains information on the following:

- Legislation that applies in Great Britain
- The role of the MHRA
- Requirements for those manufacturing and supplying devices in Great Britain
- Registrations in Great Britain
- UK Responsible Person
- UKCA mark and Conformity Assessment Bodies
- CE marking and Notified Bodies
- Labeling requirements
- Post-market surveillance and vigilance
- Regulation of medical devices in Northern Ireland
- Placing a medical device on the EU market

(ii) UK MHRA Inviting Public Comments on Possible Changes to the Regulatory Framework for Medical Devices in the United Kingdom

The UK MHRA published a consultation document on 16 September 2021, inviting members of the public to provide views on the future regime for medical devices in the UK.

It is proposed that the new regulatory framework will come into force on 1 July 2023 with appropriate transitional arrangements. In making changes to the regulatory framework for medical devices, the MHRA will ensure that we use both regulations and guidance to establish a fluid and effective approach to the oversight of medical devices and technologies.

In some cases, this is likely to involve greater use of guidance than under the existing regulatory framework to ensure that we can keep pace with dynamic innovation in medical technologies, whilst maintaining high standards of patient safety.

Below is the structure of the new regulation:

- Chapter 1: Scope of the Regulations
- Chapter 2: Classification
- Chapter 3: Economic Operators
- Chapter 4: Registration and UDI
- Chapter 5: Approved Bodies
- Chapter 6: Conformity Assessment
- Chapter 7: Clinical Investigation / Performance Studies
- Chapter 8: Post-market Surveillance and Vigilance
- Chapter 9: In Vitro Diagnostic Medical Devices
- Chapter 10: Software as a Medical Device
- Chapter 11: Implantable Devices
- Chapter 12: Other Product-Specific Changes
- Chapter 13: Environmental Sustainability and Public Health Impacts
- Chapter 14: Routes to Market
- Chapter 15: Transitional Arrangements
- Chapter 16: Feedback
- Chapter 17: Questions for Members of the General Public
- Appendix

2.3. USA

(i) US Proposed Guidance Document on Content of Premarket Submissions for Device Software Functions

This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. It identifies the software information generally necessary for evaluating the safety and effectiveness of a device in a premarket submission. The recommendations in this guidance also may help facilitate FDA's premarket review.

The recommendations in this guidance document pertain to device software functions, including software in a medical device (SiMD) and software as a medical device (SaMD). When final, this document will replace FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on 11 May 2005, and it will update FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

2.4. Brazil

(i) Publication of Resolution RDC No. 579 on Importation, Marketing and Donation of Used and Reconditioned Medical Devices

This resolution defines the requirements for import, marketing and donation of used or reconditioned medical devices intended for use in the national territory. The activity of technical assistance is not part of the scope of this regulation.

Chapter II deals with the prohibitions and according to Article 4, are prohibited the importation, marketing, and donation of used or reconditioned medical devices that do not comply with the requirements established.

Chapter III mentions the commercialization and donation of used equipment and, among other things, determines that the used equipment must have an indelible label preserved in order to allow traceability and identification of its regularization number at Anvisa.

The resolution contains the following provisions:

- Chapter IV on the technical report for marketing and donation of used equipment
- Chapter V on reconditioning of equipment
- Chapter VI on the use after expiration of regularization

(ii) Publication of Resolution RDC No. 551 on Mandatory Execution and Notification of Field Actions by Medical Device Registration Holders

This Resolution defines the situations in which the execution and notification of field actions by health product registration holders in Brazil are mandatory. The registration holders must fulfil the following obligations:

- To initiate a field action whenever there is sufficient evidence or proof that a health product does not meet the essential safety and efficacy requirements applicable to it
- To indicate the need to suspend the marketing/importation of the affected batch or series, unless defined by the National Health Surveillance System (SNVS)
- To draw up, implement and keep up-to-date written operating procedures for the field actions under its responsibility

- To disclose an alert message relating to a field action under its responsibility, expressed in a clear and objective manner and containing, as a minimum, information on:
    - The problem
    - The product (registration/notification number, product name, model and batch/series affected)
    - The risk related to the problem
    - Guidelines for health professionals, patients, users, the regulated sector, other interested parties or the community in general
- To select and use the most effective means of communication for dissemination of the alert message
- To submit the message to ANVISA within 5 calendar days from the decision to carry out the field action in case it is necessary to use a mass media vehicle to disseminate the alert message
- To notify Anvisa of the field's performance action involving the health product under its responsibility, in accordance with the established deadlines and conditions
- To submit to ANVISA monitoring reports and field action conclusion reports
- To send to the registration holder the distribution map and other information requested for the notification and execution of field actions
- To provide assistance to users, patients or other persons involved, in order to make the risk associated with the product use acceptable and reduce the effects of damage already occurred, in cases where the health product subject to field action has been or is still being used
- To maintain an up-to-date archive of documents and records relating to its field actions, structured so as to ensure traceability of information and rapid retrieval of data and information

(iii) Publication of Resolution RDC No. 546 on Approving Technical Regulation on Essential Safety and Performance Requirements for Medical Products

This resolution applies to medical products defined as "related" under Law No. 6.360/1976 with the exception of in vitro diagnostic products. The safety and performance requirements specified therein shall be met by both manufacturers and importers. Medical products shall meet the essential requirements of Articles 6 and 9 taking into account the purposes intended by their manufacturers.

Evaluation of compliance with the essential safety and performance requirements should be based on clinical data, particularly for Class III or IV medical products.

(iv) Publication of Regulations on Quality Control of Certain Products

- Portaria No 485/2021 on Approval of Conformity Assessment Requirements for Surgical and Non-Surgical Procedure Gloves

- Resolution RDC No. 541/2021 on Establishing Minimum Identity and Quality Requirements for Single-use Sterile Hypodermic Syringes
- Resolution RDC No. 547/2021 on Establishing Minimum Identity and Quality Requirements for Certain Surgical Gloves and Gloves for Non-Surgical Procedures
- Resolution RDC No. 552/2021 on Registration, Manufacturing, Quality Control, Marketing and Use of Intrauterine Devices (IUDs) Containing Copper

2.5. South Korea

(i) South Korea Issued Amendments to Medical Device Act with Respect to Manufacturers and Importers' Obligations

Under Act No. 18319/2021, the manufacturers and importers of medical devices prescribed by the Ordinance of the Prime Minister among any of the following medical devices must seal containers or packages of the medical devices:

- Medical devices inserted into the human body
- Medical devices that may be contaminated or deteriorated when distributed in an opened state

The act inserts more obligations of manufacturers, importers, and distributors including training of quality managers, prohibition of sales rebates, and liability insurance for damage caused by the use of medical devices.

The act also amends the provisions on penalty surcharges of the base law so that manufacturers or importers of dangerous medical devices may be fined up to twice the price for the hazardous products.

On 17 August 2021, Act No. 18446 was enacted to amend the Medical Device Act on manufacturing license renewal and reexamination of medical devices:

- Separation of re-examination into "post-market investigation" and "follow-up measures following post-market investigation"
- Exemption from post-marketing investigation of newly developed medical devices with low risk to the human body
- Administrative sanctions and penalties for those who manufacture and import medical devices whose validity period has expired without renewing the manufacturing license

(ii) South Korea Proposed Amendments to Enforcement Decree and Enforcement Regulations of Medical Device Act on Obligations of Manufacturers and Importers

On 1 September 2021, the South Korean Ministry of Food and Drug Safety (MFDS) proposed a draft decree to amend the Enforcement Decree of the Medical Device Act by adding

standards and procedures for the imposition of fines for manufacturing harmful medical devices. Manufacturers or importers of hazardous medical devices, including unlicensed medical devices, may be subject to a penalty within the range multiplied by twice the selling price, by the sales volume from the date of first sale of the medical devices to the date of detection.

Shortly after, the MFDS proposed a draft decree to amend the Enforcement Regulation of the Medical Device Act to reflect the recent amendments made to the Medical Devices Act in relation to postmarket surveillance and medical device sealing systems.

2.6. Vietnam

(iii) Vietnam Published the Decree No. 98 on Medical Devices Management, 2021

This decree prescribes the management of medical equipment, including ensuring quality, safety and effective use of medical equipment, as well as traceability of medical equipment. Chapter II describes classification of medical devices, and chapter III describes manufacturing of medical equipment production. This decree also covers clinical research medical devices, circulation, purchase and sale, export, import, and service provision of medical equipment; information, advertising medical equipment; price management of medical equipment and management and use of medical equipment at medical facilities.

This decree deals with the principles of medical equipment management and medical devices production, which involves:

- Conditions for quality control of medical equipment manufacturers
- Dossier of declaration of eligibility to manufacture medical equipment
- Requirements for declaration of eligibility to manufacture medical equipment
- Procedures for declaration of eligibility to manufacture medical equipment

2.7. Saudi Arabia

(i) Publication of Executive Regulations on Medical Devices and Supplies

The royal decree applies to the following activities:

- Design and manufacture of medical devices and supplies
- Import, marketing, distribution and storage of medical devices and supplies
- Compliance and quality verification services of medical devices and supplies
- Validation of clinical studies
- Technical advisory services in the field of medical devices and supplies
- Medical devices and supplies inspection services that aim to ensure compliance with technical regulations and standards
- Maintenance services for medical devices and supplies

- Factory representatives from outside the Kingdom

The executive regulations add the following activities:

- Establishments that carry out the activities mentioned above electronically
- Facilities that import and export medical radioactive materials, medical imaging materials, or particle accelerators
- Facilities that export medical devices and supplies
- Overlapping products (i.e. products which contain one or more components that are subject to the regulation)
- Cosmetic devices and products that have medical applications (the authority will publish an updated list of these devices)
- Cosmetic contact lenses
- Particle accelerators used in the formation of radioactive isotopes for medical applications
- Therapeutic biological products that are not genetically modified

(ii) Publication of a List of Guidance Documents

- Guidance on Obtaining a Local Factory License for Medical Devices and Medical Products
- Guidance on Licensing of Representatives for Foreign Medical Device Manufacturers
- Guidance on Obtaining a License to Import and Distribute Medical Devices and Medical Products
- Guidance on License to Import and Distribute Optical Medical Devices

3. Product Safety - List of Rules on Classification of Medical Devices

3.1. Australia

- Guidance Document on Reclassification of Medical Devices in Direct Contact with the Heart, Central Circulatory and Central Nervous Systems
- Guidance Document on Reclassification of Medical Devices that are Substances Introduced into the Human Body
- Guidance Document on Reclassification of Surgical Mesh Devices
- Guidance Document on Classification of Active Medical Devices (including software-based medical devices)

3.2. China

- Catalogue of Class I Medical Devices, Announcement No. 158, 2021

3.3. EU

- Guidance Document MDCG 2021-24 on Classification of Medical Devices

3.4. India

- Classification of Medical Devices pertaining to Neurology, Notice No. 29/Misc./03/2020-DC, September 2021
- Classification of Medical Devices Pertaining to Oncology, Notice No.29/Misc/03/2020-DC (153), September 2021
- Classification of Medical Devices pertaining to Pain Management, Notice No. 29/Misc/03/2020-DC(178), September 2021
- Classification of Medical Devices pertaining to Gastroenterology, Notice No. 29/Misc./03/2020-DC (182), September 2021
- Classification of Medical Devices pertaining to Personal Protective Equipment, Notice No. 29/Misc/03/2021-DC (186), September 2021
- Classification of Medical Devices pertaining to General Hospital, Notice No. 29/Misc./03/2020-DC (193), September 2021
- Classification of Medical Devices Pertaining to Software, Notice No. 29/Misc./03/2020-DC (198), September 2021

3.5. Philippines

- Circular No. 2021-017 on List of Class A Medical Devices, Circular No. 2021-017

3.6. Saudi Arabia

- Guidance Document on Borderline Products Classification, Version 2.0, November 2021

3.7. South Korea

- Amendments to Classification of Medical Device and Class by Product on Adding New Medical Devices

3.8. USA

- Gastroenterology-Urology Devices - Classification of the Transcutaneous Electrical Continence Device, Final Rule, 21 CFR 876, 2021
- Neurological Devices - Classification of the Cerebrospinal Fluid Shunt System, Final Rule, 21 CFR 882, 2021
- Neurological Devices - Classification of the Diagnostic Neurosurgical Microscope Filter, Final Rule, 21 CFR 882, 2021
- Medical Device De Novo Classification Process, Final Rule, 21 CFR 860, 2021
- Guidance for Industry and Food and Drug Administration Staff, De Novo Classification Process, October 2021

4. Rules and Guidance on Certification and Registration of Medical Devices

4.1. UK

On 1 January 2022, the UK updated its guidance document on how to register medical devices to reflect changes to medical device registration requirements that will take effect on 1 January 2022.

In particular, manufacturers based outside of the UK must appoint a single UK responsible person to take responsibility for all of their medical devices. The accounts of any former Great Britain-based authorized representatives that have not updated their role to the UK responsible person on the MHRA registration system, as well as the accounts of any represented manufacturers, will be suspended from 1 January 2022 until the UK responsible person has updated their role. Furthermore, a Northern Ireland-based authorized representative will no longer be able to register devices on a manufacturer's behalf for the Great Britain market from 1 January 2022.

4.2. Brazil

(i) Publication of Resolution RDC No. 545 on Electronic Protocol for the Issuance of Certificates of Notification and Registration of Medical Devices

This resolution lays down provisions on electronic protocol for issuing a product certificate (certificate of notification or registration of a medical device) and certificate for foreign government (certificate of notification or registration for export of a medical device), according to the models contained in annexes I and II of the resolution.

The documents issued will be valid until the expiry of the notification or registration of the products, except for the invalidated notification or registration. It is prohibited to make any changes to the documents issued. In the case where there are inconsistencies found in the information relating to the medical device covered, the company must notify Anvisa through the link of the electronic protocol.

The issuance of the product certificate and the certificate for foreign government shall be made via electronic protocol, in accordance with the models set out in annexes I and II. In addition, the resolution outlines the procedure for applying for a certificate.

(ii) Publication of Resolution RDC No. 549 on Procedures for the Compulsory Certification of Equipment Under the Health Surveillance Regime

According to the resolution, equipment under the health surveillance regime shall be subject to mandatory certification within the scope of the Brazilian System of Conformity Assessment (SBAC). The certification shall be carried in accordance with Resolution RDC No. 546/2021 and concerns the following equipment, including their parts and accessories:

- Equipment with medical, dental, laboratory or physiotherapeutic purpose, used directly or indirectly for diagnosis, treatment, rehabilitation and monitoring of human beings
- Equipment with beautification and aesthetics purposes

The suppliers of equipment under the health surveillance regime shall submit, for the purposes of obtaining, amending or renewing registration for these products, a copy of the certificate of conformity issued by an accredited body within the scope of the SBAC. The testing and certification process of equipment under the health surveillance regime shall be carried out in accordance with the applicable ANVISA's regulations on conformity assessment for these products.

The certification procedure described in this resolution is intended to establish the safety and effectiveness and the above equipment. It shall not be considered as the only applicable procedure as additional studies and analyses may be required under Resolution RDC No. 546/2021.

4.3. China

(i) Publication of Order No. 47 on Administrative Measures on Registration and Filing of Medical Device

This order lays down provisions on filing and registration, product technical requirements, registration inspection, clinical evaluation, documentations and procedure of registration and filing.

Class I medical devices are subject to filing management. Class II and Class III medical devices are subject to registration. Supplementary documents for filing and registration shall be in Chinese. If the translation is based on foreign language, the original text should be provided at the same time.

The medical device registration certificate is valid for 5 years. These measures entered into force on 1 October 2021, and the Administrative Measures on Registration of Medical Device was repealed.

(ii) Publication of Announcement No. 157 on Emergency Approval Procedures for Medical Devices

The emergency approval procedures are introduced as a response to public health emergencies. It applies to medical devices that are not in the domestic market and in need for public emergencies, as well as domestic Class III devices and imported Class II and Class III devices. It does not apply to medical devices for emergency use that are covered by the Order No. 739 on Supervision and Administration of Medical Devices.

Applicants must submit the "Application Form for Emergency Approval of Medical Devices" and product research summary and relevant instructions to the acceptance department of the State Food and Drug Administration. The validity period of the medical device registration certificate, in principle, will not exceed one year. If the registrant completes the attached conditions, renewal of registration can be applied for before the expiration date.

(iii) Publication of Principles for Registration Review of Combination Products

This document applies to drug-device combination products with primary intended use as medical devices. It guides the applicants through the registration requirements and provides detailed information on special requirements for registration of combination products, including:

- Electronic application
- Product description
- Effect of the medical device and drug
- Drug dossier and selection
- Chemical and physical function
- Biology feature
- Product technical requirements
- Manufacturing information
- Clinical trial requirements

(iv) Publication of 6 Guidelines for the Registration and Technical Review of Medical Devices

On 11 January 2022, China's National Medical Products Administration published 6 guidelines for medical device registration and the reference for the technical review department regarding the following types of medical devices:

- Disposable high-pressure angiography syringes and accessories
- Metal bone plate internal fixation system
- Degradable magnesium metal orthopedic implants
- Microcatheters
- Disposable endoscopic injection needles
- Intraocular lens

4.4. South Korea

South Korea published amendments to regulations on medical devices authorization and reporting requirements. The amendment makes changes to definitions, procedures, scope of applicable standards, and reporting requirements for the purpose of medical device certification and licensing.

- Clarification of the definition of “same product group" (Article 2): a new provision is added that medical devices that differ only in the sterilization method or packaging method related to the manufacturing method, can be regarded as the "same product group"
- Introduction of a definition of "pre-review" (Article 2): "pre-review" involves reviewing the availability of data to be submitted prior to formal review of applications for medical device approvals
- Introduction of procedures for changing the use of medical devices approved for exhibition (Article 58-2)
- Expansion of the scope of accreditation of safety test standards recognized in medical device approval/certification procedures (Article 17, Article 29)
- Introduction of video and face-to-face meetings for applicants seeking approvals for new development/rare medical devices (Article 62-3)
- Expansion of reporting requirements with the MFDS to minor changes prescribed under Article 19 (e.g. changes in packaging units, changes in model names, etc.)

4.5. Singapore

Singapore issued a list of guidance documents on the registration of medical devices:

- Guidance on Medical Device Product Registration, Guidance (Revised)
- Guidance on Contents of a Product Registration Submission for In Vitro Medical Devices using the ASEAN CSDT (Revised)
- Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic Medical Devices using the ASEAN CSDT(Revised)

- Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT (Revised)
- Guidance on Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT (Revision 1.3)

4.6. Russian Federation

Russia published Order No. 885n on Approving the Procedure for Medical Device Conformity Assessment.

The Conformity Assessment in the form of technical tests, toxicological studies, and clinical trials for the purpose of state registration of medical devices shall be carried out in accordance with the procedures set out in this order.

Testing and medical organizations can not be in any way dependent on the developer or manufacturer (manufacturer) of a medical device or other persons interested in the results of tests (research).

4.7. MERCOSUR

MERCOSUR published Technical Regulation for Registration of In Vitro Medical Devices, Resolution MERCOSUR/GMC/RES. 24/2021. Manufacturers and importers of in vitro medical devices and their accessories (defined in annex 1) from the MERCOSUR states parties must comply with this resolution. The resolution lays down provisions on definitions, classification, registration procedure, conformity of information, and sanctions for the purpose of registration.

This document is not applicable to used or refurbished medical devices. In vitro medical devices intended for clinical research are exempted from registration.

This regulation shall be adopted by all MERCOSUR states parties by 11 April 2022.

5. Conclusion

2021 saw a high level of regulatory activity across medical devices, particularly in the EU, USA, UK and Asia. Developments in the product safety of medical devices will continue to evolve as we see increased innovation and dependence on medical devices around the globe.

Interested in finding out more? Register here for our upcoming webinar '**Product Safety of Medical Devices: Reviewing the Regulatory Landscape**'.

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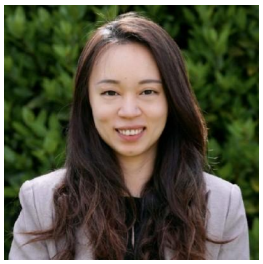

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She helps product manufacturers to identify and understand the regulations in place in the markets to which they sell by helping them to map their obligations with regard to product safety (chemicals, EMC, radio frequency), labeling, energy efficiency, waste and packaging.

Amy is a native Chinese speaker and has a Master of International Commercial Laws from the University of Limerick, and a Bachelor of Law degree from University College Cork.

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