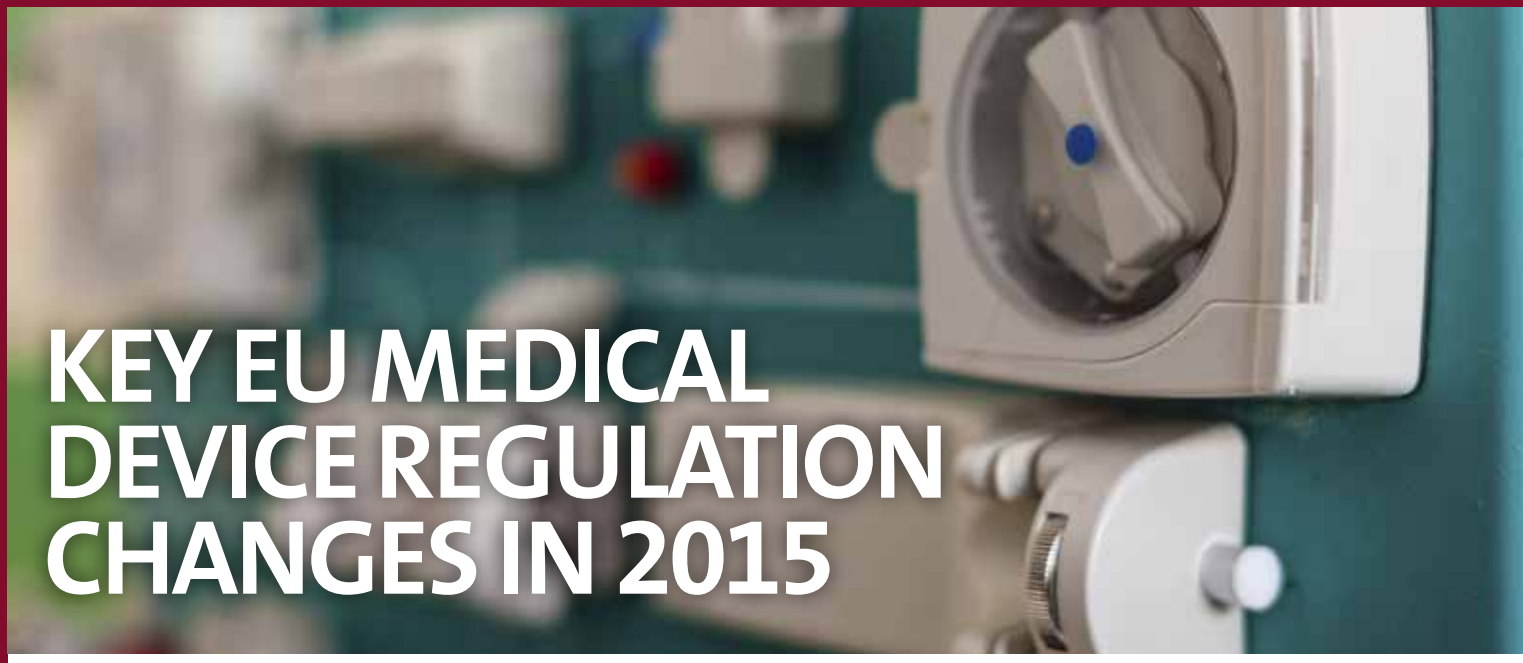
Life & Health

Medical Device Communiqué

Q2 2015



KEY EU MEDICAL DEVICE REGULATION CHANGES IN 2015

Earlier this year, UL Health Sciences conducted a webinar, The New Medical Device Regulation – Impact and Outlook on the Future. The webinar featured UL technical expert, Jochen Wegerer, who outlined the critical MDR changes and how they affect manufacturers currently selling or planning to sell devices in the EU.

- Merge of AIMDD and MDD
- Integration of contents of the GHTF and the MEDDEV
- 10 chapters with 93 articles altogether (currently, the MDD contains 23 articles)
- Extension of scope to further products
- More definitions, e.g.: Sponsor
- New assessment of classifications
- Designation of a qualified person by the manufacturer
- Expansion of EUDAMED
- Class III devices: EUDAMED publication
- Involvement of competent authorities and expert groups in class III devices
- Annex II for technical documentation
- Implementation of EU reference laboratories
- Implementation of the UDI
- Centralized system for safety reporting and vigilance
- Centralized submission process with multi-centric clinical investigations

Listen to the webinar recording at web.ullifeandhealth.com/The_New_EU_MDR

(continued...)

KEY EU MEDICAL DEVICE REGULATION CHANGES IN 2015 *(Continued)*

UL EduNeering continues to focus on covering key EU GMP, regulatory and compliance topics, including new courses being developed today. All of our key EU courses are listed below, and courses scheduled for release in 2015 are noted. The courses are segmented by these areas: "Corporate Compliance," "EU Submission Process" and "EU GMP Regulations."

Medical Device Directive/CE Mark:

- EU Medical Device Directive: Part I – Introduction (MDD01): This course provides basic information concerning the European Medical Device Directive and the CE marking of medical devices.
- EU Medical Device Directive: Part II – Specific Procedures (MDD02): This course explains the technical requirements associated with MDD, such as device classifications, clinical data, post-market surveillance, technical knowledge and increased transparency.
- CE Certification for Medical Devices (MDD03): This course provides information on the compliance of the medical devices in accordance with the MDD and the In Vitro Diagnostic Directive (IVDD). *This course is expected to launch in Q3 2015.*

GMP Basics:

- A Tour of Health Europe: (PHDV90)
- Batch Record Reviews: (EU) (PHA53-EU)
- Change Control (EU): (PHA35-EU)
- Environmental Control and Monitoring (EU): (PHDV87-EU)
- Failure Investigations for Pharmaceutical Manufacturers (EU): (PHA59-EU)
- Good Distribution Practices: *This course is expected to launch in Q2 2015.*
- Good Documentation Practices for Medical Device Manufacturers: (DEV56)
- Gowning for Sterile Manufacturing (EU): (PHA63-EU)
- Principles of Aseptic Processing (EU): (PHDV71-EU)
- Principles of Sterilisation (EU): (PHDV81-EU)
- Principles of Good Documentation: (PHA74)
- Qualified Person (Annex 15): *This course is expected to launch in Q3 2015. We discuss a portion of this course in this Communique.*
- Understanding the GMP Requirements for Facilities and Equipment (EU): (PHDV63-EU)

IT Validation:

- EU GMP Requirements for Computerised Systems (PHDV95): This new course explains the requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

Inspection Readiness:

- EU Directives and Inspection Readiness (PHDV96): This new course explains the regulatory background regarding EU inspections, the expectations inspectors may have and how to prepare for inspections.

Laboratory Control:

- Application of GMPs to Analytical Laboratories (EU) (PHDV78-EU)
- Application of GMP to Microbiology Laboratories (EU) (PHDV72-EU)

Packaging and Labeling:

- Care and Handling of Medicinal Product Starting Materials and Packaging Materials (EU): (PHA41-EU)
- Packaging and Labeling of Finished Pharmaceuticals (EU): (PHA39-EU)

If you are interested in these courses, please contact your Account Director, or contact Pat Thunell at Pat.Thunell@UL.com.

CE CERTIFICATION FOR MEDICAL DEVICES: MDD'S SIX GENERAL REQUIREMENTS

MDD considers a medical device safe and effective if it meets the essential requirements that can be found in Annex I of the MDD. All devices regardless of class or route to conformity must meet these 14 essential requirements. The first six are general and the final eight involve design and construction concerns. The six categories of the general requirements include:

- 1 and 2 – Patient Safety
- 3 – Performance Achievement
- 4 – Safety in Use
- 5 – Transport and Storage
- 6 – Risk or Benefit

In this article, we examine these six general requirements, as they are always applicable, regardless of a device's construction.

We are currently adding a new course on CE Certification for Medical Devices, written by UL Life and Health experts who conduct a number of consulting services for our medical device clients.

Scheduled to be launched later this year, the course will provide information about compliance with the MDD. After completing this course, learners will be able to recognize essential requirements and harmonized standards of the MDD and the IVDD Directive. They will also be able to identify the quality systems, documentation and language that is specific to these directives.

CE CERTIFICATION FOR MEDICAL DEVICES: MDD'S SIX GENERAL REQUIREMENTS *(Continued)*

1 and 2 – Patient Safety

The MDD contains two clauses on patient safety:

Clause 1: "The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety."

Clause 2: "The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted."

Essential Safety: When dealing with essential safety, it is important to ask the following questions:

- Will the device operate without compromising the safety or health of the patient?
- Does the device conform to all specifications?
- What is the device intended to do?
- Is there potential to harm the patient?
- What is the experience with the device?
- Is there a process of considering risk control options?

3 – Performance Achievement

Medical devices "must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2)(a), as specified by the manufacturer." The device must also be designed, made and packaged so it meets its specifications as a medical device. Lastly, the device must be part of the risk management process.

Device Lifetime: The MDD also indicates that the performance of the device must not be adversely affected by the stresses occurring in normal use during the lifetime of the product as defined by the manufacturer. Lifetime Measurements include:

Shelf Life: The shelf life of a product (e.g., sterile products) is dependent on how long that product can be stored before the integrity of the packaging is breached and the device is no longer sterile or safe to use.

Lifespan: The lifespan of a product (i.e., failure of equipment) is the length the device can be used before it will have a failure that results in unacceptable risk to the patient or operator. The lifespan must be made known to the user within the instruction manual and must be part of the risk management process. The lifespan of a product must be measured in time, not in the number of uses. Lifespans can take into account the mean time to failure of critical components, based on a specified use.

Support: Another aspect of a product's lifetime to consider is how long the manufacturer will support it (e.g., provide service or components for it).

CE CERTIFICATION FOR MEDICAL DEVICES: MDD'S SIX GENERAL REQUIREMENTS *(Continued)*

4 – Safety in Use

Aligned with the ISO 10993 standard, MDD's safety in use requirement requires that companies evaluate the biological response of materials or devices as a part of the overall evaluation and development of the products. The product should be studied on the biocompatibility and toxicity of its materials, for example, and a safety evaluation should assess the risk of adverse health effects during routine use.

5 – Transport and Storage

MDD requires that performance of a device cannot be adversely affected by its transportation or storage. Considerations include:

- Design (i.e., product and packaging).
- Mode of transport.
- Storage conditions.
- Post market surveillance (i.e., experience and complaints).

Performance during transport and storage: "The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer."

6 – Risks or Benefits

Risk of undesirable side effects of the use of the device should be weighed against the performance intended (i.e., benefits to the patient). It is important to consider the risk analysis for new products and post market surveillance (e.g., experience and complaints) for existing products.

For the eight design and construction requirement categories, which will be covered in our new course, a manufacturer must state how it shows compliance with each design and construction requirement. The manufacturer should also state why any of these requirements does not apply to your device.

An essential requirements checklist will help a manufacturer summarize compliance. The method of complying with the essential requirements is the choice of the manufacturer, and each company can use standards to show that the device meets one or more essential requirements.

If you are interested in our EU MDD course series, which will include this new CE Certification course later in 2015, please contact your Account Director, or contact Pat Thunell at pat.thunell@ul.com. For more information about UL's CE Mark consulting services, send an e-mail to HealthSciencesNA@ul.com.

UL HEALTH SCIENCES WORKSHOPS

As part of the UL Life and Health group, UL EduNeering is continually seeking to expand our "blended learning" educational programs, which include both live workshops and eLearning courses.

For example, the following programs are offered via UL and partner organizations, and clients can include our eLearning courses as prerequisites for the face-to-face workshops. These workshops can be scheduled privately at your company location for a minimum of six attendees.

Some of the workshops below are managed by leading training firm Oriel STAT A MATRIX, which is a partner to UL and has conducted consulting, training and assessment/auditing services for organizations of all sizes, from Fortune 10 companies to 10-person operations. Companies choose Oriel STAT A MATRIX for consulting, training and assessment/auditing services related to US FDA, EU Medical Directives, ISO 13485, ISO 14971, ICH Q10 and Management Systems, including ISO 9001, AS9100, ISO 13485, ISO/TS 16949 and ISO 14001. Learn more at www.orielstat.com.

To sign up for any of these workshops, visit the UL Knowledge Services at: lms.ulknowledgeservices.com

Click the "Workshops and eLearning" link on the left, then the "Health Sciences" button.

Workshops for Engineers:

Designing for Compliance to IEC 60601-1 3rd Edition

- 6/10/2015 Toronto, ON - UL
- 8/26/2015 Dallas, TX
- 10/13/2015 Princeton, NJ

Measurement, Control and Laboratory Use Equipment: Designing for Compliance to IEC 61010-1 3rd Edition

- 9/22/2015 Melville, NY – UL

Workshops for QA/RA:

The CE Marking: Strategies for European Compliance

- 5/27/2015 Chicago, IL
- 9/15/2015 Buffalo, NY

Internal Auditor Training for ISO 13485

- There are 10 locations and dates throughout 2015

Lead Auditor Training for ISO 13485

- There are 10 locations and dates throughout 2015

Implementing Design Control Requirements and Best Practices

- 6/1/2015 Boston, MA
- 7/13/2015 Indianapolis, IN
- 8/10/2015 Edison, NJ
- 9/21/2015 San Diego, CA
- 10/19/2015 Chicago, IL
- 11/30/2015 Boston, MA

Process Validation Principles and Protocols

- 6/1/2015 Indianapolis, IN
- 7/13/2015 Boston, MA
- 8/10/2015 Chicago, IL
- 9/14/2015 Edison, NJ

Risk Management for Medical Devices: Compliance with ISO 14971

- 9/9/2015 Austin, TX
- 10/6/2015 Brea, CA

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.