Webinar – UKRP Services

2020-11-13

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Before We Start…

- The webinar is one hour in total, appr. 40 min. presentation and remaining time for Q&A
- Post questions about the webinar topics in the Q&A window
- Other stuff, technical issues, etc, in the chat window
- Cameras and microphones are turned off/muted by host
- The webinar is recorded

Disclaimer

The Brexit negotiations between the European Union (EU) and the United Kingdom (UK) is still ongoing and current planned regulatory amendments may be adjusted

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Webinar - UKRP Services

1	**Brexit**
2	Upcoming Changes in Medical Devices Regulations 2002
3	UK Conformity Assessment (UKCA)
4	UK Responsible Person (UKRP)
5	Timeline
6	UKRP Services by QAdvis
7	Advice for Manufacturers

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Brexit Timeline

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Upcoming Changes in Medical Devices Regulations 2002

- Introduction of a new marking system – “UK Conformity Assessed” (UKCA) marking
- CE marking phased out
- Introduction of the role “UK Responsible Person” (UKRP)

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Other Activities In the Regulatory Landscape

- Releasing new standards, for example:
  - **DCG-0129**: Clinical Risk Management: its Application in the Manufacture of Health IT Systems
  - **DCG-0160**: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

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“UK Conformity Assessed” (UKCA) Marking

- Conformity Assessment with respect to the UK Medical Devices Regulations 2002 (UK MDR 2002)
- Available for manufacturers from 2021-01-01
- “UK Conformity Assessment Bodies” issues UKCA certificates
- Valid in England, Scotland and Wales
- In Northern Ireland special rules apply
  - CE marking continues to be recognized
  - UKNI marking must in some cases accompany the CE mark
  - But… the situation around NI still vague and uncertain

Still subject to parliamentary approval

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Phase Out of CE Marking

- CE marked medical devices will continue to be accepted on the UK market until 2023-06-30
- Both MDD (AIMD, IVDD) and MDR (IVDR) are recognized
- Valid in England, Scotland and Wales
- In Northern Ireland special rules apply
  - CE marking continues to be recognized
  - UKNI marking must in some cases accompany the CE mark
  - But… the situation around NI still vague and uncertain

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“UK Responsible Person” (UKRP)

- The role of the UKRP is to serve as the manufacturer’s liaison and contact point with the MHRA
- Must have a registered place of business in the UK
- Should be designated at the latest 2021-01-01
- Must be disclosed to MHRA at the latest when a manufacturers’ devices are registered (grace period of 4-8-12 months depending on risk class)
- UKRP no longer defaulted to importer, it must be actively designated
- Name and address of UKRP on labeling at the latest when a UKCA mark is attached

Still subject to parliamentary approval

UKRP Role Definition According To MHRA 1(2)

- Ensure that the declaration of conformity and technical documentation have been drawn up
- Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate
- Register manufacturers' devices at MHRA
- In response to a request from the MHRA, provide all the information and documentation necessary to demonstrate the conformity of a device

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UKRP Role Definition According To MHRA 2(2)

- Provide samples of a device to the MHRA or allow the MHRA access to the device
- Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents
- Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under the applicable Regulations and inform the MHRA

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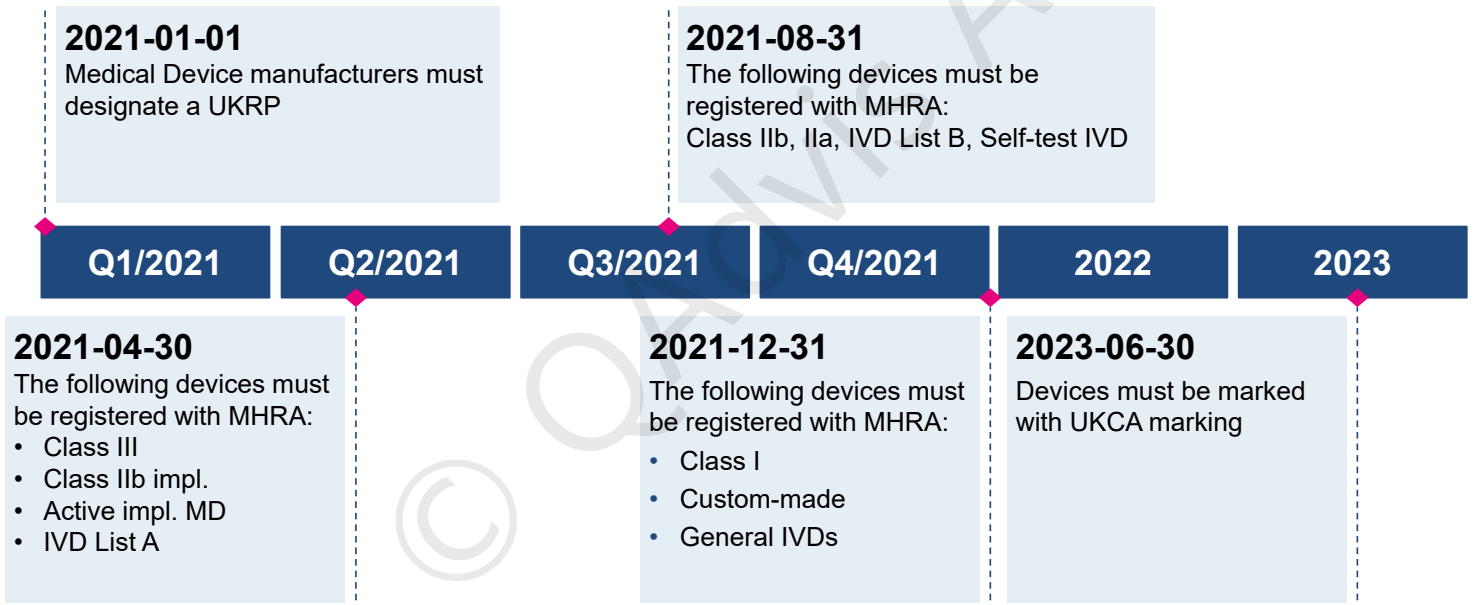
UKRP and UKCA Timeline



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UKRP Services Offered by QAdvis

- Initial review of the technical documentation and declaration of conformit
  for each product, or product family (up to 10 variants), to ensure
  compliance with the UK MDR 2002
- Issue review report

Initial

- Registration of manufacturer and devices in MHRA's Device Online Registration System (DORS
  including updates/changes/withdrawals
- Issue of UKRP certificate (if requested)

Fixed Fee

- Keep available, and safeguard, a copy of the technical documentation for each product, or family of products
- Act as liaison and contact point for MHRA
- Inform manufacturer about updates and changes to the regulatory landscape within the UK
- Grant the right to manufacturer to use QAdvis UK Ltd's name and address on the product labeling

Annual

- Optional services may be requested for additional regulatory guidance and support (will be quoted separately)

Optio-nal

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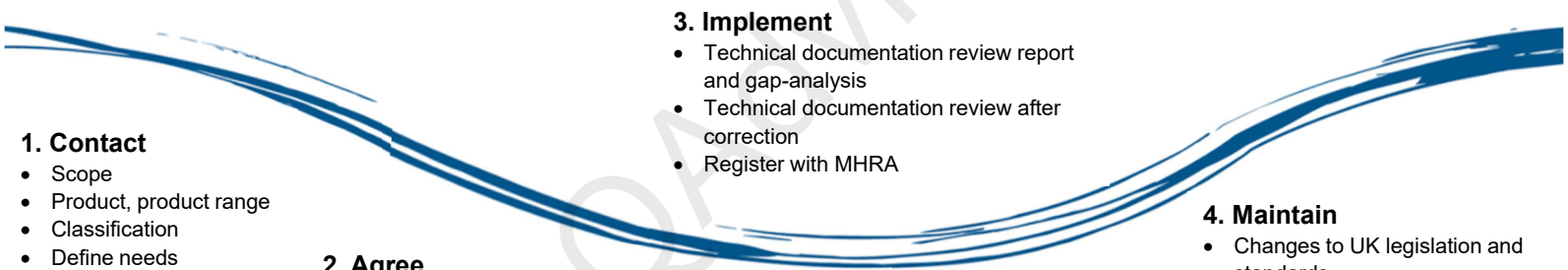
The Process From Contact to Maintenance



1. Contact
- Scope
- Product, product range
- Classification
- Define needs
- Quotation

2. Agree
- Define roles & responsibilities
- Access to, and review of, technical documentation
- Written agreement
- Mandate

3. Implement
- Technical documentation review report and gap-analysis
- Technical documentation review after correction
- Register with MHRA

4. Maintain
- Changes to UK legislation and standards
- Changes of scope and product range
- Renewals of MHRA registrations
- Support in MHRA communication

Why QAdvis?

- 10 years of experience from very similar setup with our European Authorized Representative services
- Easy access and communication for Scandinavian manufacturers, including our team of regulatory professionals
- Good relationship with MHRA, our EAAR-org will be able to provide comments to draft MHRA guidelines
- Independent professional UKRP focusing on regulatory aspects, not distribution/supply chain

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Advice for Manufacturers

- ☑ Designate a UKRP before 2021-01-01
- ☑ Consider an independent professional UKRP focusing on regulatory aspects, not distribution/supply chain
- ☑ Understand the development of a new UK regulatory landscape and start planning for UKCA as soon as possible
- ☑ Avoid potential shortage of UK Conformity Assessment Body similar to EU NB shortage

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Contact

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