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# European Regulatory Roundup, September 2021: EN ISO 13485 Updated And More Key Implementation Developments

by Amanda Maxwell

The big news in September was the update of the EU medical quality management system standard to link it for the first time with the new regulations on medical devices and IVDs. Many Medical Device and IVD Regulation foundation stones are now falling into place, but critics remain concerned.

The European version of the international medical device quality management systems standard, EN ISO 13485:2016+A11:2021, has been updated with new annexes demonstrating the link between specific clauses of the standard and the general safety and performance requirements (GSPR) of the Medical Device and IVD Regulations. It is expected to be published in the Official Journal of the EU in October, making it a "harmonized" standard. Manufacturers that follow harmonized standards are presumed to be in conformity with the requirements in the regulation with which they are linked.

Another vital standard for the medtech industry on risk management, EN ISO 14971, is also expected to be updated in the same manner very soon.

Another particularly significant development in  September has been that the latest version of the European medical device database, Eudamed, became temporarily unavailable at the end of the month. Industry anticipates that this means the European Commission is in the process of adding in two new modules on UDI/device registration and on certificates and notified bodies to join the already available module on actor registration. All these modules will be available on a voluntary basis until the database becomes fully operational in May next year.

## Further Implementation Developments

Other news related directly to the implementation of the MDR and IVDR is that TÜV Rheinland Italia became the *23rd notified body* to be designated under the EU Medical Device Regulation, and the fifth in Italy.

Also, the European Commission has returned from its traditional August break to work on a *series of legal acts to support implementation of the MDR and IVDR*. Its work will include common specifications, effectively mandatory technical standards, for IVDs and for Annex XVI products without an intended medical purpose, such as dermal fillers and liposuction equipment; and rules and fees for EU reference laboratories that, among other things, play a key role in the assessment of high-risk IVDs.

The regulatory round-up for August is available *here*.

## 'Pedantic' Application Of MDR Damaging Europe

Conference season is underway again and Elizabeth Gfoeller, corporate director, regulatory affairs at MED-EL, *told the RAPS Convergence meeting* about her concerns of Europe becoming "competitively backward" not least because "there was "no real possibility for industry to actively and meaningfully engage in drafting EU guidances" and also due to the "pedantic" application of the MDR.

She spoke of inexperienced reviewers and lack of predictability at notified bodies and "timelines for projects … all over the place". Bassil Akra, CEO of Akra Team, concurred in a *recent interview with Medtech Insight*, saying that notified bodies' accelerated hiring and training of staff to support their activities has meant a lack of experience when it comes to applying the auditing theories.

Many reviewers take a checklist, get bogged down in the less important issues, ask many more questions than should be necessary and their inexperience can lead to files being closed unnecessarily, he explained. This means manufacturers having get at the back of a long queue to resubmit files and the result is delays in much-needed products reaching the market, he said.

## Where Is Notified Body Capacity?

The added issue, of course, is the lack of auditing capacity at notified bodies. As demand grows and is on the point of escalating, finding a notified body with bandwidth is becoming increasingly difficult. What is needed is *a central repository or a website* that can identify which notified bodies can take on new clients in which product areas.

The issues with capacity have been so acute, that for the German medtech industry, the 20th German Bundestag election has been relegated in importance by the market access problems

being caused by the EU regulations. Marc-Pierre Möll, head of the BVMed industry association, pointed out that "*dramatic bottlenecks" in notified body capacity* are still being seen. He warned of a serious backlog in EC certificate issuance in the coming years.

## Regulatory Future Under Review As EMA Involvement Grows

During September, Medtech Insight featured a series of pieces highlighting how the changing rules within the MDR relating to drug/device combinations or borderline products have become *a catalyst for further regulatory change*.

The European Medicines Agency has become more interested and involved in the regulation of products that include medical device aspects and there are questions about whether its role now go further than combination products given that moves are now underway for the *EMA to play a role related to expert panels* that review high-risk medical devices and IVDs.

With the spotlight strongly focused on innovation and on the interplay between devices and drugs, the commission is now calling for *another round of legislative changes for combination products and discussions are starting to intensify*.

## New Classification Process For Tricky Devices

Borderline and combination products can create challenges when it comes to whether there are classified as a device or not and, if so, under what risk classification. The same challenges can apply to the risk classification of products that are clearly devices.

To aid decision-making and create a time-frame and transparency to the process, the Medical Device Coordination Group (MDCG) has updated a process known as the Helsinki procedure. Most decisions should now be made within a six-month time-frame.

In the UK, meanwhile, the Medicines and Healthcare products Regulatory Agency has published its *consultation document on the future regulation of medical devices and IVDs*. Comments on the document will be accepted until 25 November 2021. The *consultation* is split up into 17 chapters covering key areas of regulation. These include, for example, "Scope of the regulations", "Classification" and "Economic Operators" etc. Within the chapters, there are a total of 83 areas on which comments are being invited.

## Top 10 EU Regulatory Stories

| Rank | Title |
|---|---|
| 1 | ***EN ISO 13485 Linked To MDR and IVDR At Last*** |
| 2 | ***How The MDR Is Making The EU Competitively Backward*** |