Medical Devices

Frequently Asked Questions: IVD Panel Webinar

1. **What will the requirements be for the new Qualified Person position?**
   This has not yet been defined. There are two potential models the requirements for the German Safety Officer and the pharma QP, and the expectations are quite different. Another key question is whether contract QPs will be allowed. This is especially important because there is a limited pool of experts with more than two years IVD regulatory experience.

2. **What is a reasonable timeline expectation for the transition period?**
   The recent report from the IVD Rapporteur recognizes the limited number of subject matter experts in the IVD field, and therefore a long transition period is needed. However, it also emphasizes the urgent need to change the regulations. It is hoped that the five year transition in the current draft will remain; there are some calls to align the IVD transition period with the Medical Device Regulation transition period of three years. It is possible that some elements, such as registration and possibly vigilance, could be introduced more quickly, but the regulation allows five years for products to meet the new conformity assessment requirements.

3. **In your opinion, what effect, if any, will the 2014 European Parliament elections have on the regulations, and their implementation?**
   There is significant political pressure to see changes to both the IVD and medical devices directive promptly achieved. We expect every effort to be made to complete this legislation before Parliament is dissolved for reelection. While this is an ambitious timetable; there is a sufficient focus to achieve.

4. **How do Notified Bodies plan to execute random inspections?**
   a. **Will IVD manufacturers be subject to unannounced audits in the same way as medical device manufacturers?** Yes

   b. **Are there any differences in the frequency of unannounced audits with respect to IVD classification (in particular General IVDs)?**
      BSI will start unannounced visits once we have received direction from the “Commission Recommendation on the audits and assessments performed by notified bodies in the field of medical devices.” This is expected to be published shortly, and also as directed by MHRA. This only relates to Notified Body activities, so self certification devices will not be affected. However, once the regulation is applied, many more IVD products will require a Notified Body, and fall under this requirement.

We expect that unannounced visits will be required at least once every three years depending on the risk of the device, and also the company's compliance record. We expect the frequency for Annex II List A devices will be once every two years. This is inline with Class III medical devices which is once every three years for Annex II List B, and annually if there are compliance issues. Visits may be to the manufacturer, critical suppliers, or subcontractors.

c. **How will random inspections be remunerated?**
The regulations require manufacturers to pay for the visit and expenses incurred for additional measures required to safeguard the security off the assessment team.

d. **Do you feel that Notified Bodies have the bandwidth to commence this additional service?**
This will be a requirement of Notified Body designation, and therefore Notified Bodies will be required to have sufficient resources, and expertise to perform this new activity.

e. **What are the estimated implementation dates (voluntary versus mandatory) for unannounced Notified Body audits for IVD manufacturers?**
We currently expect that these requirements will become effective from January 2014.

5. **For Class C Companion Diagnostics, you indicated Competent Authority Consultation will be required, what do you expect this will entail? For example, could the consultation require that a Design Dossier was required? What will the Notified Body and manufacturer involvement be?**
The IVD Technical Group has established a Companion Diagnostic subgroup; this will develop guidance, and identify what technical documentation will need to be provided to the drug Competent Authority. The conformity routes available to class C do not require a design dossier; however, they will need to be provided with some technical documentation.

6. **When the Notified Body gets involved for devices that they were not previously involved with, will all those impacted devices require the Notified Body number with the CE mark?**
All devices will need to undertake the appropriate conformity routes before the end of the transition period, and where a Notified Body is required, this will require the application of the CE mark with the appropriate Notified Body number on labelling and IFUs.

7. **What is the mechanism to make the summary of the directive available to the public?**
The summary of safety and performance required for class C and D devices will be submitted with the registration.

8. **Does this apply to all IVD manufacturers or just those based in the United States?**
The requirements of the regulation will apply to all devices sold in the European Economic Area.