

## EDMA Workshop on the Implementation of the IVD Regulation

**13 and 14 October 2016**

*Renaissance Brussels Hotel  
Rue du Parnasse 19, 1050 Bruxelles*

THIS IS A 1 AND A HALF DAY WORKSHOP: FULL DAY ON 13 OCTOBER AND  
HALF DAY ON 14 OCTOBER

### THIS WORKSHOP IS FREE OF CHARGE AND OPEN TO:

- EDMA Corporate Associate Members (CAMs)
- IVD industry members (manufacturers) and staff of the National Association Members (NAMs) affiliated to EDMA
- EDMA Associate Members

*Please distribute this invitation within your company or among your members.*

***The number of persons per company is not limited. EDMA reserves the right to limit the number of participants on a first-come, first-served basis.***

On 25 May 2016, the Council and European Parliament announced that they had reached a 'political agreement'. A consolidated text of the IVD Regulation has been made available which is expected to be essentially the same as the IVD Regulation text which will be officially published early 2017. This means that we can plan now for implementation of the IVD Regulation based on the consolidated text which is already available today.

EDMA is organising this workshop to present the main changes from the directive to the regulation which will impact business. Participants will discuss the priorities for industry in approaching implementation of the regulation.

---

To register, please complete the registration form and send it back to [Kacper Olejniczak](mailto:Kacper.Olejniczak@edma.eu) by Friday 30 September 2016. Registrants will receive a confirmation letter by email.

A dinner on Thursday 13 October will be coordinated by EDMA for interested participants – more details will follow soon.

# preliminary draft Agenda

Thursday 13 October

<b>09:30</b>	<b>Registration and Coffee</b>
<b>10:00</b>	<b>Welcome</b>
<b>10:15</b>	<b>IVD Regulation – what is the state of play?</b>
<b>10:35</b>	<b>Overview - key changes from Directive to Regulation</b>
<b>11:15</b>	<b>Transitional measures</b>
<b>12:00</b>	<b>Q&amp;A</b>
<b>13:00</b>	<b>Lunch</b>
<b>14:00</b>	<b>Priorities for implementation</b>
<b>15:00</b>	<b>Break-out sessions on priorities</b>
<b>16:30</b>	<b>Conclusions</b>
<b>17:00</b>	<b>End of Day 1</b>

Friday 14 October

<b>9:00</b>	<b>Welcome back to Day 2</b>
<b>9:15</b>	<b>How to prepare for implementation</b> <ul style="list-style-type: none"><li>➤ <i>View from a country</i></li><li>➤ <i>Approach from an individual company</i></li><li>➤ <i>International perspective</i></li></ul>
<b>10:15</b>	<b>Q&amp;A</b>
<b>11:30</b>	<b>Roundtable discussion</b>
<b>12:30</b>	<b>Conclusions and closing statements</b>
<b>13:00</b>	<b>Lunch</b>
<b>14:00</b>	<b>End of Workshop</b>

