



ROMA CONVENTION CENTER-LA NUVOLO

**IBA 2018**



**ROME 7-12 OCTOBER**

ANNUAL CONFERENCE OF THE INTERNATIONAL BAR ASSOCIATION

# Final Programme



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## IBA 2018

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### Title

**Safety, market surveillance and transparency: the new EU regulations on medical and in-vitro diagnostic medical devices**

### Location

Session Room G, Level -1

### Date

Thursday 11 October (1115 - 1230)

### Committee(s)

International Sales Committee - (Lead)  
Healthcare and Life Sciences Law Committee

### Session / Workshop chair(s)

Monika Gattiker

LANTER, Zurich, Switzerland; European Regional Forum Liaison Officer, Healthcare and Life Sciences Law Committee

Laura Opilio

CMS Adonnino Ascoli & Cavasola Scamoni, Rome, Italy; Vice Chair, International Sales Committee

### Description

Cases like Theranos and Poly Implant Prosthèse (PIP) caught the attention of the public and triggered discussions in the industry, among notified bodies and authorities. The European Union reacted by replacing the former Active Implantable Medical Devices (AIMD), Medical Devices Directive (MDD) and In-Vitro Devices Directive (IVDD) with the Medical Devices Regulation (MDR) and In-Vitro Devices Regulation (IVDR). The new regulations entered into force on 26 May 2017 and shall apply after graduated transitional periods, ranging from 6 months to 5 years, in Spring 2020 (MDR) or Spring 2022 (IVDR), respectively. What changes do the new regulations bring? What difficulties do manufacturers face with the new rules? How does the work of the notified bodies change with the new regulations? Will it be more difficult to place innovations on the market under the new regulations? Will the costs increase for innovations under the new rules?

## Speakers

Federica Albiero Philips S.p.a., Milan, Italy
Jeffrey Gibbs Hyman Phelps & McNamara, Washington, District of Columbia, USA
Bei Ma Global Healthcare Business Development, Washington, District of Columbia, USA
Professor Antonio Olivia Università Cattolica del Sacro Cuore (Policlinico Gemelli), Rome, Italy
Giorgio Rizzello Johnson & Johnson, Diegem, Belgium
Thomas Wejs Møller Danish Medicines Agency, Copenhagen, Denmark

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