

## **PL-1.5**

## Medical Devices Regulations, Management and Assessment; New Trends new Needs

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In the accelerated way that Medical Devices (MDs) are developed and revolutionize health care delivery during the last decades, Regulation, Management and Assessment of Health Technology are of paramount importance. This paper provides a short overview of the recent development in this area and discusses some issues related to the new EU regulatory framework on MDs, the need for a more rigorous management and the importance of Health Technology Assessment for MDs. Study is also focusing on the particular characteristics of MDs that impose a different approach, in these three domains, compared to medicinal products, in order to get the expected benefits right to the patients, in a safe and cost-effective way.