



Institute for
Pharmacy Practice
and Policy

Subject: SIR ERA Course 2019-2020 – starting in May!

Dear colleagues and friends,

With great enthusiasm we are pleased to inform you that the ERA-course is now open for registration.

The course will consist of four modules, which take place in 2019 and 2020:

8 – 10 May 2019	Module A: Foundations of the EU regulatory system
9 – 11 October 2019	Module B: Quality and pre-clinical part of the dossier
15 – 17 January 2020	Module C: Clinical part of the dossier
4 – 6 March 2020	Module D: On the edge of pre- and post-marketing

Considered a great success over the past years, the SIR ERA course is viewed by leading authorities as an established learning vehicle for professionals in regulatory affairs, both in industry and government.

Whether you need a good regulatory and scientific knowledge base on which to build, or you wish to update your European regulatory affairs experience this course will perfectly match your needs!

In this 12-day course, distributed over 4 modules we will review the drug development process as well as the different components of the regulatory dossier.

New in our program are subjects as “the integration between marketing authorization and health technology assessment (HTA)” and patient involvement and innovative regulatory concepts such as Medicines Adaptive Pathways to Patients (MAPPs”).

Additional information about the ERA course, including objectives for each module, fees and practical information (including registration), can be found at www.sir-era.eu.

Feel free to forward this e-mail to colleagues and friends who may be interested!

For any questions, please mail t.m.bakker@sirstevenshof.nl or call 0031(0)715766157.

Best wishes,

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Course director

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