FDAnews Announces — FDA and EU Inspections: The Mutual Recognition Agreement: What’s Next? Webinar, Sept. 27, 2019

It’s been seven years since the FDA and EU began moving toward cooperative inspections but that day has arrived. Here’s what one needs to know.

FALLS CHURCH, Va. (PRWEB) September 13, 2019 -- FDA and EU Inspections
The Mutual Recognition Agreement: What’s Next?
**An FDAnews Webinar**
Friday, Sept. 27, 2019, 1:30 p.m. – 3:00 p.m. EDT
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Who’s that knocking on the door? The FDA ... or someone else?

Don’t rule out ‘someone else.’ Under the new Mutual Recognition Agreement (MRA), investigators from any of the 28 EU member states have the right to inspect global drugmakers’ operations.

And foreign inspectors may be the least of the company’s concerns. Now that the MRA is fully implemented at last, companies face new issues including: pros and cons of relying on EU inspections, potential for increased efficiency across the board, and next steps as the U.S. and EU enter a new era of cooperation.

Compliance consultants Cynthia Schnedekar Esq. and Elizabeth (“Liz”) Oestreich Esq. are the guides for a 90-minute survey of the post-MRA world. Attendees will discover:

• MRA Timeline: The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 and what it has led to
• Benefits so far: How inspectors are using each other's inspections to maintain a risk-based approach ... potential benefits for U.S. drug safety
• And costs: How the MRA may complicate regulatory and compliance operations ... which inspections FDA will continue to perform ... which will go to EU member states
• What’s next for: FDA capability assessments ... possibility of duplicating the MRA model in other regions ... potential impact of ‘Brexit’ on the MRA

Full implementation of the MRA only took place this July so there’s still lots to learn. If the organization sells drugs into EU nations — or anywhere in this interconnected world — one will want to mark the calendar for this timely presentation.

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