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New handbook for production of Water for Injection

Guideline explains and helps implement the regulations

Amended European guidelines open up new approaches for the production of Water for Injection. The new regulations nonetheless raise questions about how to implement the new process. An expert group within the International Society for Pharmaceutical Engineering (ISPE) has taken on the issue and developed a common understanding of the manufacturing process requirements.

The European Pharmacopoeia Commission decided in 2016 to permit use of the cold method for the manufacture of Water for Injection (WFI), which is utilized primarily to produce injection and infusion solutions. Since coming into effect in 2017, the new resolution allows European manufactures to use not only conventional distillation processes but also energy-efficient membrane methods such as those already permitted in the US and Japan.

New methods promise more safety and efficiency
While experts see an opportunity to produce WFI with a greater degree of safety and lower energy costs with the new process, the amendment to the regulation brings with it an abundance of new regulatory requirements for pharmaceutical companies. In order to minimize risk, for instance, WFI systems are subject to continuous monitoring and must satisfy strict engineering requirements.

“The guidelines leave a lot of room for interpretation. If a pharmaceutical manufacturer implements every single aspect in accordance with the legal regulations, distillation is still the more cost-effective option,” says Fritz Röder, expert within the ISPE group for pharmaceutical water and steam for the German/Austrian/Swiss region and head of the WFI manual project.

Handbook serves as aid to implementing the guidelines
An expert team within the ISPE, which is involved in issues related to production systems and processes for pharmaceutical water and pure steam systems, has now created a guideline that describes what the legal regulations mean for the production of WFI. Specialists from various disciplines contributed extensive expert knowledge to the 110-page handbook, which is intended to serve as an orientation guide for plant and pharmaceutical manufacturers, as well as government representatives.

Stefan Raabe, Strategic Account Manager at Endress+Hauser and a member of the expert team, who boasts years of first-hand experience in planning and implementing pharmaceutical water systems, underscores the necessity of the guideline: “The handbook provides answers to a wide range of unanswered questions related to the membrane-based production of WFI. Pharmaceutical manufacturers and regulatory authorities around the world can use this manual to design their water systems and produce medications for patients in a safe, effective and affordable manner.”

The manual is available in hardcover in German via the ISPE homepage.

EH_WFI_Handbook.jpg
Guideline for the production of Water for Injection – the newly published ISPE Handbook.

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