PDA Global Headquarters
Bethesda Towers,
Suite 600
4350 East West Highway
Bethesda, MD 20814 USA
TEL: +1 (301) 656-5900
FAX: +1 (301) 986-0296

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin
Germany

April 15, 2019

World Health Organization
Medicines Quality Assurance
kopps@who.int
jonessi@who.int

Reference: Production of Water for Injection by Means Other Than Distillation (February 2019) Draft Guidance

Dear World Health Organization:

PDA appreciates the opportunity to respond to World Health Organization Consultation on: Production of Water For Injection By Means Other Than Distillation. PDA fully supports the WHO's Production of Water for Injection by Means Other than Distillation (February 2019) Draft Guidance, as it advocates a risk-based lifecycle approach. The WHO Draft Guidance deems to incorporate latest changes in European Pharmacopeia and other global regulatory and standards guidances. PDA supports flexible approaches for products currently manufactured to avoid interruption of supply of essential medicines. PDA is also working to harmonize language across guidances as a global effort to increase the implementation of standard processes.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in pharmaceutical manufacturing and pharmacopeia publications including members representing our Board of Directors and our Science Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson
President, PDA
Cc: Tina Morris, Falk Klar, Janie Miller

Comments on WHO Working Document QAS/...
Title of the document : PRODUCTION OF WATER FOR INJECTION BY MEANS OTHER THAN DISTILLATION (Working document QAS/19.786)

World Health Organization

Comments submitted by : Parenteral Drug Association (PDA)
Telephone number : 001-301-656-5900
Address : 4350 East West Highway, Bethesda MD, 20854 (USA)
Email : miller@pda.org

Date : 15April2019

Template for comments

*Kindly complete the table **without modifying the format** of the document - thank you.*

General comment(s) if any :	**Originator of the comments**
PDA fully supports the WHO's PRODUCTION OF WATER FOR INJECTION BY MEANS OTHER THAN DISTILLATION (February 2019) Draft Guidance, as it advocates a risk-based lifecycle approach. The WHO Draft Guidance deems to incorporate latest changes in European Pharmacopeia and other global regulatory and standards guidances. PDA supports flexible approaches for products currently manufactured to avoid interruption of supply of essential medicines.	PDA

# section	Line no.	Comment / Rationale	Proposed change / suggested text	Classification L= low M= medium H= high	Originator of the comments (for WHO use)
7	165	This statement is aspirational. Firms that do not have distillation experience in the same setting and with the same feed water may find this challenging to demonstrate.	The purification process must be proven to meet the compendial requirements for water for injection.	M	PDA
5.4	107	The risk is never eliminated but controlled.	Risk of contamination of water is controlled.	M	PDA
6.1	118	The risk is never eliminated but controlled. Also then ties into the 6.2 where it states to reduce risks to an acceptable level.	Risk of contamination of WFI produced, stored or circulated is controlled.	M	PDA
7.7	176	The risk is never eliminated but controlled. where it states to reduce risks to an acceptable level.	Risk of contamination of WFI produced, stored or circulated is controlled.	M	PDA

Comments on WHO Working Document QAS/…
Title of the document : PRODUCTION OF WATER FOR INJECTION BY MEANS OTHER THAN DISTILLATION (Working document QAS/19.786)

World Health Organization

Comments submitted by : Parenteral Drug Association (PDA)
Telephone number : 001-301-656-5900
Address : 4350 East West Highway, Bethesda MD, 20854 (USA)
Email : miller@pda.org

Date : 15April2019

Template for comments

*Kindly complete the table **without modifying the format** of the document - thank you.*

General comment(s) if any :	**Originator of the comments**
PDA fully supports the WHO's PRODUCTION OF WATER FOR INJECTION BY MEANS OTHER THAN DISTILLATION (February 2019) Draft Guidance, as it advocates a risk-based lifecycle approach. The WHO Draft Guidance deems to incorporate latest changes in European Pharmacopeia and other global regulatory and standards guidances. PDA supports flexible approaches for products currently manufactured to avoid interruption of supply of essential medicines.	PDA

# section	**Line no.**	**Comment / Rationale**	**Proposed change / suggested text**	**Classification** **L**= low **M**= medium **H**= high	**Originator of the comments (for WHO use)**
7	165	This statement is aspirational. Firms that do not have distillation experience in the same setting and with the same feed water may find this challenging to demonstrate.	The purification process must be proven to meet the compendial requirements for water for injection.	M	PDA
5.4	107	The risk is never eliminated but controlled.	Risk of contamination of wáter is controlled.	M	PDA
6.1	118	The risk is never eliminated but controlled. Also then ties into the 6.2 where it states to reduce risks to an acceptable level.	Risk of contamination of WFI produced, stored or circulated is controlled.	M	PDA
7.7	176	The risk is never eliminated but controlled. where it states to reduce risks to an acceptable level.	Risk of contamination of WFI produced, stored or circulated is controlled.	M	PDA