Cytiva
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Regulatory support for BioProcess™ equipment

Cytiva is committed to support our customers to effectively fulfil regulatory requirements valid for equipment designed to be used in regulated environments e.g., BioProcess™ systems, columns and mixers.

Cytiva recognizes the importance to provide requested regulatory documentation and has regulatory specifications for equipment intended for use in regulated environments. The Material conformity (MC) and Material certificate report (MCR) show that the materials used in parts, that are in contact with the process fluids/medical product (product contact materials) and/or are pressure retaining, are compliant with the regulatory requirements. MC and MCR are included in the product documentation at the delivery of the BioProcess equipment. The regulatory specifications for the main equipment also cover spare parts and accessories. Material certificates are included in each delivery.

The applicable regulatory requirements are:

- Animal derived component free (ADCF*)* or in compliance with EMA/410/01 - *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*
- In compliance with USP <88> Class VI - *Biological Reactivity tests, In Vivo* or ISO 10993 *Biological evaluation of medical devices*; ISO 10993-6, -10/-23, -11 (the three parts together)
- In compliance with USP <87> *Biological Reactivity Tests, In Vitro* or ISO 10993-5 *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
- In compliance with Code of Federal Regulations (CFR), Title 21 Food and Drugs, Part 177 Indirect Food Additives: Polymers
- Tested in alignment with BioPhorum Best Practices Guide for Extractables Testing of Polymeric Single-Use Components Used in Biopharmaceutical Manufacturing." and/or <*USP 665*> *Plastic components and systems used to manufacture pharmaceutical drug products and biopharmaceutical drug substances and products.*

Moving forward and as part of Cytiva´s policy shift regarding biocompatibility compliance, Cytiva will no longer require USP <88> Class VI compliance for product contact materials (PCM). Cytiva will instead support biological reactivity compliance through either existing USP <88>, USP <87> or their ISO 10993 equivalents. Additionally, Cytiva will no longer require FDA 21 CFR part 177 compliance for PCM in new and revised equipment, spare parts, and accessories. Products that currently fulfil this requirement will remain compliant until further notice.

For older products and product families released before 2006, Cytiva is not always able to support with required regulatory documentation.

Extractables information, based on the total extractable of the main equipment, is available for download after subscription on www.cytiva.com/rsf.

For description of the regulatory requirements, Cytiva´ s interpretation and compliance with the requirements for each platform, see the Attachment.

Equipment not designed for use in regulated environments (laboratory products and some process development products) are not specified with regulatory material requirements and cannot be supported with material certificate documentation.

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Sara Corin

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Attachment

A description of the regulatory requirements, the interpretation, and compliance for each platform are listed in Table 1 and 2. These requirements are applied to materials used in parts that are in contact with the process fluids/medical product (product contact materials) and/or are pressure retaining.

Table 1: Description of the regulatory requirements and Cytiva' s interpretation

Regulatory requirements	
ADCF *or* EMA 410/01	The applicable polymeric or elastomeric material used in both raw material and manufacturing process is Animal derived component free (ADCF) or compliant with EMA/410/01 - *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.* For metals, glass, and ceramics compliance is only valid for the manufacturing process. A part is in firsthand ADCF or in second hand in compliance with EMA/410/01 or a combination of the two for a multi-material part.
USP <88> Class VI *or* ISO 10993-6, -10/-23, -11 (In vivo test)	The applicable polymeric or elastomeric material is compliant with USP <88> Class VI *Biological Reactivity Test In Vivo,* or ISO 10993 *Biological evaluation of medical devices;* ISO 10993-6, -10/-23, -11 (the three parts together). Testing in compliance with ISO 10993-10 pre 2021 and ISO 10993-23 2021 and later, is accepted.
USP <87> *or* ISO 10993-5 (In vitro test)	The applicable polymeric or elastomeric material is compliant with USP <87> *Biological Reactivity Tests, In Vitro* (cytotoxicity test*)* or ISO 10993-5 *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
FDA 21 CFR 177	The applicable polymeric material is compliant with Code of Federal Regulations (CFR), Title 21 Food and Drugs, Part 177 Indirect Food Additives: Polymers
BioPhorum Best Practices Guide *or* USP <665> (Extractables)	The applicable polymeric or elastomeric material is tested in alignment with BioPhorum Best Practices Guide and/or USP <665> *Plastic components and systems used to manufacture pharmaceutical drug products and biopharmaceutical drug substances and products*

Table 2: Compliance with regulatory requirements for BioProcess™ equipment

	ADCF *or* EMA 410/01	**USP <88> class VI *or* ISO 10993-6, -10/-23, -11 (all 3)**	**USP <87> *or* ISO 10993-5**	**FDA 21 CFR 177**	**Extractables information**
BioProcess columns					
AxiChrom™ columns	✓	✓	-	-	✓
Chromaflow™ columns	-	✓	-	-	✓
FineLINE™ columns	-	✓	-	-	-
AxiTide™ columns	✓	✓	-	✓	-
BPG columns	✓	✓	-	-	✓

	ADCF *or* EMA 410/01	USP <88> class VI *or* ISO 10993-6, -10/-23, -11 (all 3)	USP <87> *or* ISO 10993-5	FDA 21 CFR 177	Extractables information
Bioprocess column related products					
Chromaflow™ Packing Station	✓	✓	-	✓	-
Media handling unit	✓	✓	-	✓	-
BioProcess systems					
BioProcess™ Modular System	✓	✓	-	✓	-
BioProcess™ IC System	✓	✓	-	✓	-
ÄKTA process™	✓	✓	-	-	✓
ÄKTA™ flux 6	✓	✓	-	✓	-
ÄKTA pilot™ 600 R	✓	✓	-	-	✓
UniFlux™	✓	✓	-	✓	✓
OligoPilot™	✓	✓	-	-	-
OligoProcess™	✓	✓	-	-	-
BioProcess™ pcc	✓	✓	-	-	-
BioProcess mixers					
BioProcess™ Resin Mixer	✓	✓	-	✓	-