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cGMP Statement for InVitria Products

cGMP are guidelines provided by the US Food and Drug Administration for drugs and pharmaceuticals. InVitria operations are designed and operated with consideration to these guidelines published in Title 21 Code of Federal Regulations 21 CFR, Parts 210/211 and ISO 9001:2008. The manufacturing documentation and batch production records are according to cGMP guidelines. The equipment used in certain manufacturing processes has been qualified according to cGMP guidelines. InVitria has implemented process validation and cleaning validation for certain products. InVitria products are considered ancillary materials used in the manufacture of biologics and are not directly regulated by FDA or other regulatory authorities. InVitria products have been used in cell-based vaccines used in clinical studies and in products approved by FDA and EMA. These are included as a cell culture media component and as a formulation excipient.

Pat Smith
Director, Quality
InVitria

17APR17
Date