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Chemically-defined media have been developed for CHO cell culture platform processes. During implementation of the media at multiple scales and sites globally, additional activities were required to seamlessly balance practical considerations with desired process and product quality performance. Three main focus areas were further investigated and optimized to enable the platform implementation: 1) media preparation, filtration, and post-filtration stability; 2) media and supplement viral barrier compatibility; and 3) and raw material variability considerations. Overall, the effort provided an outlined approach for media implementation in the global network including scale and site-specific case studies where novel options were required.

The data generated supported successful implementation of chemically-defined platform media at different global sites within our network. Manufacturing-scale media preparations met acceptance criteria and resulted in comparable cell culture performance and product quality to controls. Practical challenges were identified and risk mitigation efforts initiated. The challenges were primarily related to poorly-defined media preparation mixing environments as a result of variable equipment availability and use. Filtration capacity acceptance criteria were met in the scale-down model and large-scale filtration events were successful. HTST-compatibility studies showed that HTST-treated media performed comparably to control media in cell culture performance and product quality. Post-filtration media stability investigations led to the identification of key risk factors including temperature and agitation variation during storage, nucleation and media destabilization as a result of specific handling practices, and the impact of specific process-contacting materials. Options for mitigating the media stability risks and enabling successful implementation were developed and showed no negative impact for the application. Finally, platform media modifications were developed to mitigate raw material variation and product quality challenges. The overall evolution of the media platform to ensure flexibility and successful implementation will be summarized.