



International Alliance for
Biological Standardization



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Nancy Sajjadi holds an M.Sc. degree in genetic engineering and has no formal statistics training. She has worked in the cell and gene therapy space since joining a start-up company as a bench scientist in 1989. In 2000, she left her position as Director, Quality Control and since then has worked as a consultant with more than 50 organizations involved in the development and quality control of complex, cutting-edge experimental medicines. Her interest in statistics derives from early challenges she faced in preparing assay development and validation documentation to support investigational new drug applications (INDs) at a time when there was limited guidance available. She has gained experience and insights into CMC statistics through participation on the first USP panels that drafted informational chapters address bioassay design, development, and validation as well as ongoing work helping clients address complex CMC issues to support the success of cutting-edge biologics. She has collaborated with Janice Callahan on multiple projects since 1990 and they have co-authored several publications.