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**TITLE:** Rapid Microbiology Methods (RMM) and Quality by Design (QbD)

**Abstract:** Quality by Design (QbD) is an approach for designing a drug product and manufacturing process to reliably produce a quality product. One of the key components of QbD is the use of Process Analytical Technology (PAT) to control the manufacturing process. Part of the definition of PAT is the use of timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality. Traditional microbiology methods, with their limitations in time to results, can't really be used as PAT. RMM are necessary for the implementation of PAT for microbiology. This presentation will provide a regulatory view on how RMM fits into QbD

**Bryan S. Riley, Ph.D.** is a senior review microbiologist in the Office of Pharmaceutical Science in the Center for Drug Evaluation and Research at FDA. He is involved in numerous scientific and regulatory issues relating to product quality microbiology. Dr. Riley is also a member of the FDA's Process Analytical Technology (PAT) team for Rapid Microbiology Methods (RMM). Prior to coming to FDA in 1998, he directed a specialty clinical diagnostic microbiology laboratory.



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