

the regulatory acceptance of rapid microbiological methods: "Rapid microbiological methods (RMMs) have been implemented by a number of companies around the world. In many cases, it is advantageous to work directly with regulatory authorities to fully understand their expectations for validation and submission requirements. To assist the industry in considering appropriate strategies for the validation and use of RMMs, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other global authorities have accepted and encouraged the use of RMMs. A number of guidance documents and policy changes have been developed to assist the industry in implementing rapid and alternative technologies in the laboratory and manufacturing environments. Using the links at the top of this page, you can navigate to comprehensive summaries for the most relevant regulatory guidelines"