Continuous manufacturing provides a distinct set of advantages and challenges from technical and regulatory viewpoints. Challenges such as batch definition and traceability, dynamic control strategies, use of Process Analytical Technologies, validation strategies and specifications are some of the areas which can require new perspectives from both industry and regulators. This presentation will reflect on the current regulatory environment and principles applied to continuous manufacturing; it aims to share the European experience with marketing authorisation applications using aspects of continuous manufacturing; and outlines Agency support to innovation and opportunities to consult and interact with the regulatory authorities during various stages of product development.