

Special Issue

Pharmaceutical Industry 4.0

Message from the Guest Editors

The pharmaceutical industry is under a major change in light of specific regulatory, scientific, and technological advancements. Following a long period of inaction, the pharmaceutical industry faced the first wave of change mainly originating from the regulatory authorities. The FDA's new quality initiatives started during the 1990s and focused on process engineering, introduced novel approaches for Pharma such as systems thinking in GMPs, quality by design, pharmaceutical quality system, quality risk management, continuous manufacturing, etc. This wave shaped a totally new regulatory framework, which significantly disrupted Pharma's old culture regarding, among others, its outdated manufacturing methodologies and empirical development practices.

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