

Formula 1

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Formula 2

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Formula 3

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Detailed Explanation

Sustainable Process Design (SPD) emphasizes minimizing environmental impact while maintaining economic viability and product quality across the entire process lifecycle—from raw material sourcing and synthesis through manufacturing, purification, and end-of-life considerations. The Reference Guide bridges domain-specific frameworks: ASTM standards (e.g., ASTM E3012 on green chemistry metrics and ASTM E2967 on sustainability performance indicators) provide quantifiable benchmarks for energy use, waste generation, and atom economy; ISO standards (notably ISO 14040/14044 for Life Cycle Assessment and ISO 50001 for energy management) establish systematic methodologies for evaluating and improving environmental performance; and ICH Q5 (Quality of Biotechnological Products) ensures that sustainability-driven process changes—such as alternative cell culture media or continuous purification—do not compromise product identity, purity, potency, or safety. A core principle is 'design for sustainability', which embeds eco-efficiency early in development rather than treating it as a post-hoc compliance activity. The guide supports risk-based decision-making by linking sustainability parameters (e.g., Process Mass Intensity, PMI) to quality and regulatory outcomes, enabling robust, scalable, and auditable process designs. It also facilitates harmonization across global supply chains by clarifying how overlapping requirements from different standards intersect—for instance, how ISO 14044 LCA data can inform ICH Q5 comparability assessments following a green process change.

Key Components

#	Component
1	Green Chemistry Metrics Integration
2	Life Cycle Assessment (LCA) Framework Alignment
3	Regulatory Quality-by-Design (QbD) Linkage

Applications

#	Application
1	Pharmaceutical process optimization under ICH Q5 comparability requirements
2	Biomanufacturing facility energy and solvent reduction planning per ISO 50001
3	Chemical synthesis route selection using ASTM E3012-based sustainability scoring

Related Concepts

#	Concept
1	Quality by Design (QbD)
2	Life Cycle Assessment (LCA)
3	Green Chemistry Principles

Tags

sustainability, process engineering, pharmaceutical manufacturing

ToolFusion Engineering