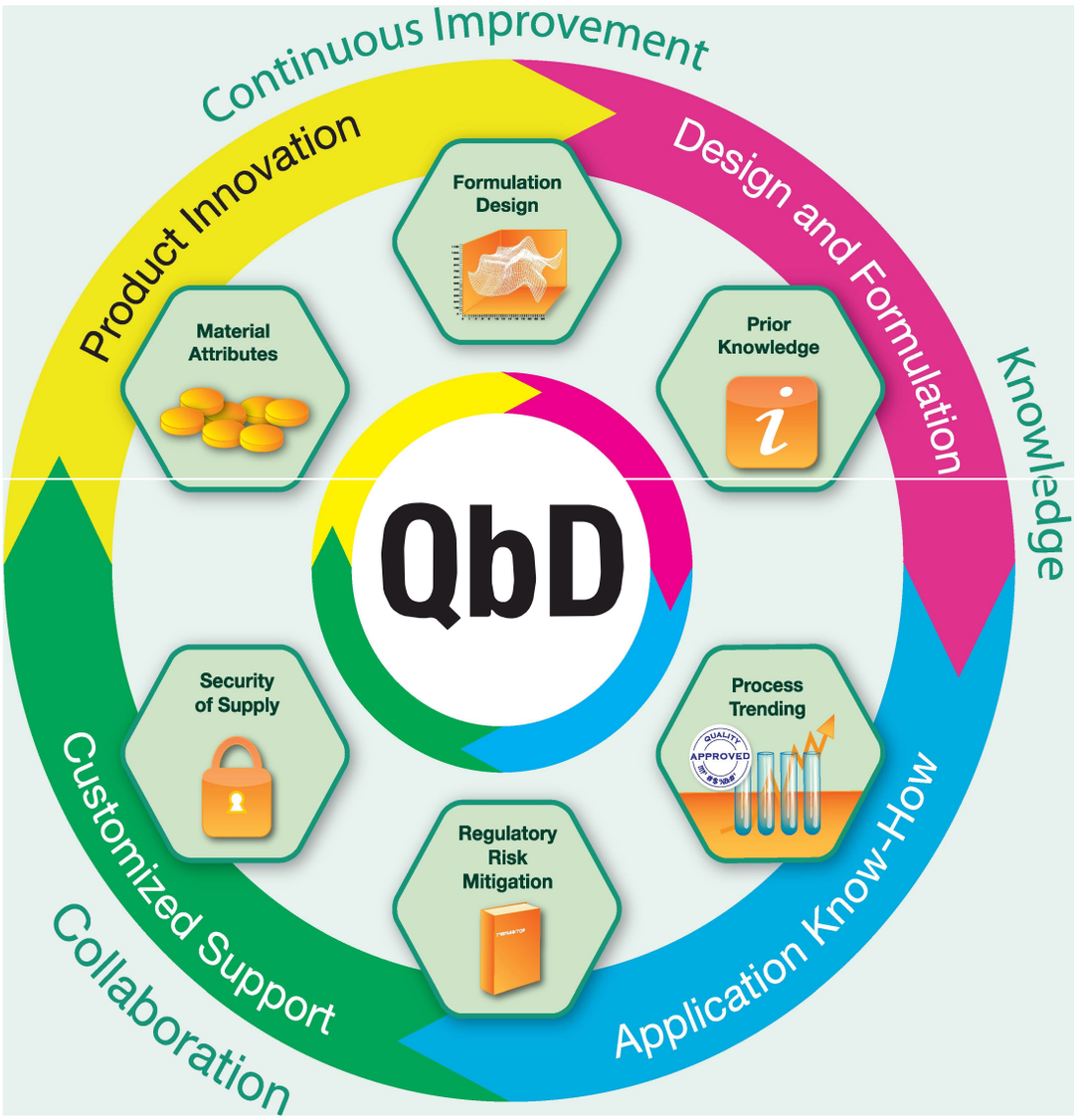
Quality by Design (QbD)
for METHOCEL™ Premium CR Cellulose Ethers

Colorcon, as Your Formulation Partner™, supports delivery of QbD approach through knowledge, collaboration and continuous improvement.



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With our Controlled Release partner IFF, Colorcon presents QbD initiatives for the robust design of product and manufacturing process of hydrophilic matrices.

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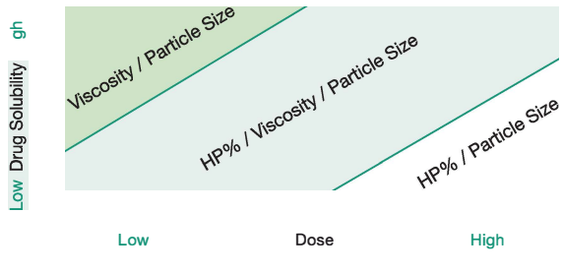
Access the METHOCEL™ Premium CR QbD Program

Identified Material Attributes (MA) for METHOCEL™ Premium CR QbD design space



Material Attributes

Identify and manage METHOCEL™ Premium CR MAs (% hydroxy propoxyl, viscosity, and particle size % through 230 mesh) for upstream quality control and consistent product performance. QbD sample library, developed by IFF, and available through Colorcon, supports proactive risk assessment of these MAs to ensure robust matrix formulation design and performance.

Formulation Design

Lower formulation risk and improve productivity in the development phase, with first time right approach. HyperStart® oral solid dose starting formulation service provides a robust and novel development process for a wide range of drug doses, solubility and release profile combinations.

Prior Knowledge

Reduce development time and resource burden through Colorcon's knowledge base, case studies and technical consultancy; including IFFpolymer expertise.

Process Trending

Manage drug product risk, using METHOCEL™ Premium CR process trend data to generate manufacturing control strategy. Limit manufacturing variability of hydrophilic matrix systems, leading to less product rejection and reduced waste.

Regulatory Risk Mitigation

Manage regulatory burden, minimize recalls and compliance actions. Meet first cycle regulatory requirements and reduce supplemental submissions, increasing speed to market. Through a number of QbD initiatives, with industry and regulatory agencies, Colorcon's global regulatory experts can help support opportunities for efficient drug product approval.

Security of Supply

Management of supply through the Colorcon - IFF Controlled Release Alliance business continuity planning, with multiple manufacturing sites for METHOCEL™ to deliver security of supply, reducing operational risk. Ensures consistent quality and availability of key materials globally.

Deliver High-Performance Products – with Colorcon

Colorcon's extensive formulation knowledge focuses on the most important factors that impact the rate of drug release: drug solubility and dose level; rate controlling polymers and the influence of other excipients. With Colorcon as Your Formulation Partner™ you can build quality into formulation design reducing the risk of final product rejection, better manage the regulatory burden and lower production cost. Colorcon continues to extend service and support to assure your first time right pharmaceutical product development.

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For more information, contact your Colorcon representative or call:

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You can also visit our website at www.colorcon.com

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