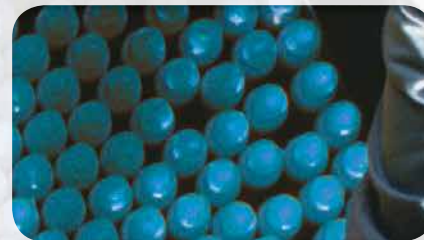
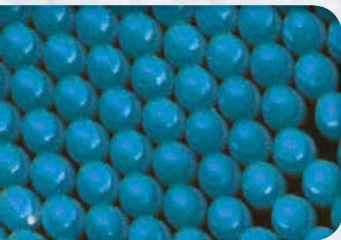
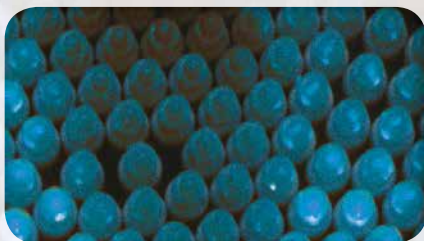


MEETING  
**CHANGE**  
WITH  
CONFIDENCE



**AVANTOR**<sup>™</sup>  
PERFORMANCE MATERIALS

# Supporting Pharma Customers through Management of Change



Avantor™ Performance Materials has developed a comprehensive Management of Change (MOC) system to keep you fully informed about changes in the supply chain of our product — such as changes to raw materials, processes or sites, to name a few of the possibilities. We know that the success of your next product can depend on the smallest details — so we have developed a robust MOC program on which you can depend.

We've classified each of our products under one of five tiers of change control notification — from the most highly regulated products, manufactured to stringent global guidelines, to non-regulated, non-cGMP materials. This makes it easier for pharmaceutical customers to select the appropriate grade of Avantor product for your processes.

## Levels of Change

Notification is based on the significance of the level of change after a review of the appropriate IPEC (International Pharmacopeia Excipient Council) guidelines. The level of change is then assigned by our quality team involved in the MOC process.

According to the guidelines:

- A **Level 1** change is considered "*Minor*" and unlikely to affect raw materials.
- Changes that are rated "*Might be Significant*" are designated **Level 2**. Customers of HR, R and RL coded products will be notified of Level 2 changes. A typical Level 2 change might involve a supplier installing new chemical extraction equipment, but without changing the process itself.
- A **Level 3** change is "*Always Significant*" and communicated to all customers of HR, R and RL coded products and to customers of NI coded products who have requested notification. Product affected by the change will be shipped unless you notify us otherwise.

The change notification levels are coordinated with our five-tier system for classifying materials and MOC procedures.

## Five-Tier Change Control Notification Classification

**1. Highly Regulated (“HR”)** — Products in this category are held to the strictest standards, covering products manufactured in accordance with pharmaceutical cGMP standards, meeting IPEC and Q7 requirements. Avantor will follow IPEC, USP and Q7 change control requirements as per Active Pharmaceutical Ingredients (APIs) for these products. Typically, an Avantor or supplier change that has the potential to alter a physical or chemical property beyond the specified limits of normal variability will result in a notification.

If you have requested change notification for “HR” products, you will receive notification of non-compendial specification changes evaluated as Level 2 or Level 3.

Products in the “HR” category include API materials such as sodium phosphate, monobasic, monohydrate.

**2. Regulated (“R”)** — This notification category includes products intended for use as Bulk Pharmaceutical Excipients (BPEs). These regulated products are manufactured in accordance with pharmaceutical cGMP standards. Customers will be notified of Levels 2 and 3 changes to an “R” product in accordance with IPEC, USP and Q7 guidelines. Typical “R” products include bulk excipients such as J. T. Baker® PanExcea™ ODT performance excipients.

For all “HR” and “R” products, we recommend that you notify Avantor of any changes in your primary contacts or the intended end use for the chemicals being supplied to you.

**3. Regulated Limited (“RL”)** — The “RL” category, created in response to Avantor customer requests, includes materials for which a true “regulated” grade does not exist. “RL”-classified products may or may not be produced under cGMP conditions, but they must have a fully traceable source. Manufacturers of

“RL” materials must follow Avantor MOC guidelines. Avantor will provide notification of change for process, manufacturing source or location change. We will notify customers of record of non-compendial specification changes evaluated as level 2 or level 3 changes.

Materials designated “RL” include the following products manufactured at Avantor facilities: Macron Fine Chemicals™ products marketed in the EU, Macron Fine Chemicals™ IP products, all biobuffers not included in the Regulated tier, FCC grade materials and materials for use in nutraceutical applications.

**4. Non-regulated with limited change information (“NI”)** — This category includes non-regulated products for which limited (but often relevant) change information is available. These products are not manufactured to pharmaceutical cGMP standards, but we require our material suppliers to provide notification of changes to these products. You will receive advance notice of a change in manufacturing source, location or warehouse site as available if you have requested registration in the MOC database. Change information for “NI” products is not always available, but is provided whenever possible, with registration. This category would cover materials such as minerals or surfactants.

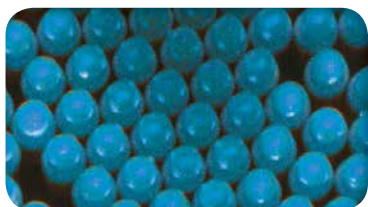
**5. Non-regulated (“N”)** — This category involves products not manufactured under cGMP standards. Change notification regarding these products is typically not available. Avantor often does not receive notification of changes from these material suppliers. This category would include products such as analytical reagents.

## The Benefits of Change Management

1. Rapid availability of important information about non-proprietary raw materials and their manufacture
2. More complete information about significant changes that could potentially impact a finished product
3. Greater sharing of key information as a result of a stronger partnership between you and Avantor, which maximizes safety for consumers, end users and patients
4. Maximized, consistent quality and reproducible process results
5. Earlier and more timely information about potential changes and their possible impact on today's global supply environment
6. More efficient use of resources, enabling you to focus on managing and reviewing the materials with the highest potential risk

## Change Notification Process Categories at a Glance

	HR	R	RL	NI	N
<b>MOC Category</b>	Highly Regulated	Regulated	Regulated Limited	Non-Regulated with Information	Non-Regulated
<b>Bulk Pharmaceutical</b>	Yes	Yes	Regional Markets	No	No
<b>Intended/Potential Use</b>	API, BPE	BPE	Processing Aids, Food, Nutraceuticals, Cosmetics	Reagents	Reagents
<b>Grades</b>	USP, NF, EP, BP, IP, JP	USP, NF, EP, BP, IP, JP	IP, EP, FCC	ACS, Reagents	ACS, Reagents
<b>Notification of Change</b>	Yes- Level 2 & 3	Yes- Level 2 & 3	Yes- Level 2 & 3	Limited if registered in MOC database	No
<b>Industry Reference</b>	IPEC, Q7	IPEC, Q7	FCC, IP, EU	None	None
<b>Regulating Body</b>	FDA, cGMP	FDA, cGMP	IFDA, EU, Food GMP	None	None



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