Supplier Product/Process Change Notification (PCN) Training
Training Goals/Objectives

• Why do we need a PCN Process?
• What changes require a PCN?
• How do I submit a PCN to CareFusion?
• What happens after I submit a PCN?
• FAQ list based on your feedback
• CareFusion PCN Point of Contact
Background

Phase II of PCN Submission Process

Phase I of PCN Process
- PCN submission tool introduced to suppliers

Current Goals -
All CareFusion suppliers submitting PCNs through process

Field Recalls
- An unapproved supplier change was implemented without CareFusion’s knowledge

Consent Decree
- CFN received an FDA Consent Decree
- Identified gap in Supplier Change Notification process

Phase 2 Goals: Increase adoption of PCN process with all suppliers
Share in CareFusion’s Vision

Our Quality Policy

The safety, quality and integrity of our products and services will be the foundation of CareFusion.

We will earn this distinction through our commitment to a best-in-class quality management system and by living our core beliefs.
Product/Process Change Notification (PCN) Requirement

- **ALL changes will be entered through CareFusion.com’s Supplier PCN Submission Form**
- **Written approval from CareFusion must be received prior to making any changes to the design or manufacture of the products we purchase from you**

**Expectations**

- **No Deviations are allowed** in the production, or testing of materials or components, unless prior documented approval is granted by CareFusion
- Verbal changes are not acceptable
- Do not assume that any changes are minor
- **Min. 90 Day Advance Notification** from implementation date when possible
- **Min. 180 Day Advance Notification** for all End of Life PCNs when possible

*Failure to obtain written approval from CareFusion for any change will result in Supplier obligation for all costs to correct problems resulting from the unapproved changes*
What Supplier changes require a PCN?

<table>
<thead>
<tr>
<th>Manufacturing Plant Environmental Conditions</th>
<th>Packaging, Labeling or Storage</th>
<th>End of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing Process, Equipment and Tooling</td>
<td>Design and/or Specification</td>
<td>Materials Supply Base</td>
</tr>
<tr>
<td>Product Name or Identification</td>
<td>Supplier Name/Company Ownership Change</td>
<td>Manufacturing Facility Site Location</td>
</tr>
</tbody>
</table>

Product/Process changes including, but not limited to this list, require a PCN submission.
Supplier PCN Submission Website

How you submit PCNs to CareFusion
1. Visit www.CareFusion.com

2. Select “Supplier Resources” under “Our Company”

3. Reference the Supplier PCN Training Deck (if needed)

4. Click here to access PCN Web Submission Form
Supplier PCN Submission Form Overview

PCN Submission Form (Enter all required fields marked with *)

Process/Product Change Notification (PCN)
All suppliers are required to notify and receive written approval from CareFusion prior to making any changes to the design or manufacture of products we purchase from you.

To better understand CareFusion's change notification requirements refer to PCN training prior to submitting the form below.

* Required
Supplier Information
Supplier Name (as stated on Purchase Order): *

Date: 09/22/2014

Provide your CareFusion Purchasing Contact name(s) for all impacted P/N’s (separated by a semicolon ‘;’) *

When do you propose that the change take place? *

[ ] / [ ] / [ yyyy

Attach a file (multiple files can be selected)
Browse...

You will need your CareFusion Purchasing Contact; start by typing their name and selecting name from drop down list

Multiple supporting change documents can be attached

Disclaimer: The receipt of a PCN by CareFusion does not signify acceptance of the proposed product or process change
You submit the PCN – now what?

1. After the PCN has been successfully submitted, you will see this message:

Within minutes, you will receive a PCN Acknowledgement email that includes a unique PCN ID # (use for PCN progress tracking).

2. PCN Acknowledgement email

3. Internal CareFusion PCN process review

Timeline will vary depending on complexity of change.

4. PCN Decision communicated to Supplier

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Q: How do I get status updates and reports on the PCNs that I have submitted?
A: Email the PCN Coordinator at GMB-CFN-SupplierPCN@carefusion.com.

Q: How long does it take to process a PCN?
A: The length of time to process a PCN will vary depending on the request. It can vary from a few days to a several months, depending on complexity.

Q: How much advance notice do I need to give on PCNs?
A: Generally, notify CareFusion as soon as possible, but the minimum expectation is a 90 day advance notification from proposed implementation date on all changes and 180 day advanced notification of last order date for all End of Life PCNs.

Q: Who can provide me with a decision on the PCN I submitted?
A: You will be notified in writing by CareFusion.
Q&A

For status inquiries or questions relating to your PCNs, please contact: GMB-CFN-SupplierPCN@carefusion.com