Data / Specification Sheet Task Group

IoPP Medical Device packaging Technical Committee

October 22, 2003

Team members

- Brett Baker, Dhuanne Dodrill, Jo Anne Forman*, Nick Fotis*, Jennifer Neid, John Ozcomert*, Geoff Pavey*, Ron Valerio,

*Attended last telecon

Recent progress

- We reviewed past progress – this was our 4th meeting. The first was a kickoff, 2nd was a review of the draft survey, 3rd was at Healthpack and 4th was to discuss the Data Sheet template guidelines:

A. Data Sheet Template Guidelines
B. Recommended Data Sheet Format
C. Data Integrity Guidelines

A. Data Sheet Template Guidelines

- Purpose: In order to provide a standardized method of presenting data sheets to speed analysis and comparison and provide the greatest engineering value, the following format and guidelines are proposed. [all agreed this was an adequate purpose.]

B. Recommended Data Sheet Format

- 1. Title and item number [add “or product code”]
- 2. Graphic description [add “pictorial depiction of layers with simple material identifiers on plies ; or pictures]
- 3. Description [add “details of structure of product; features and benefits]
- 4. Typical use [add: “applications.”]

Recommended Data Sheet Format (cont.)

- 5. Physical properties

  Property, test method, sample size, value [add “with proper significant figures”] (mean and standard deviation encouraged) [There was a lot of discussion on this topic relative to the proper use of data sheets in the process of identifying candidate materials, whether sample size was valuable or would lead to misunderstanding and the value of data sheets if actual data, mean and standard deviation were not provided. It was agreed that further discussion and input from the overall IoPP Medical Packaging Technical group would be needed.]

Recommended Data Sheet Format (cont.)

- 6. Other properties – Chemical, Toxicity, etc.
- 7. Recommended processing conditions
- 8. Marketing information [add "company information, product family marketing information.]
- 9. [Add: "Legal disclaimer"]
- 10. IoPP footer

C. Data Integrity Guidelines

1. All data used to generate information for data sheets is actual data, available for inspection. [There was disagreement about this point, see B.5 above.]

- 2. All data is gathered by standardized test methods where available. These test methods are identified on the data sheet. Where unique test methods are used, test method procedures are made readily available.

C. Data Integrity Guidelines (cont.)

- 3. Units of measure. Available. [add: "Dual units should be provided 1st column mentric, 2nd column U.S."] Recommended: translated into those usually used in the country of use.
- 4. Sample size used to generate the data is given. [There was disagreement about this point, see B.5 above.]
- 5. Recommendation – number of lots of material used to generate the data is given.

C. Data Integrity Guidelines (cont.)

- 3. Use of the “IoPP Medical packaging technical committee” footer.
- Companies may self certify compliance to this guideline document and then affix the following at the bottom of their data sheet:
- “This document is in compliance with the IoPP Medical packaging Technical committee guidelines for Data Sheet [integrity.]”

Next Steps

- 1. Continue to discuss and agree on guidelines.
- 2. To mock up sample data sheets for rollstock, pouches, bags, tapes and labels.
- 3. Sample data sheets can be forwarded to Nick.G.Fotis@cardinal.com or fax to (847) 785-2470.
- 4. Interface with FPA's Sterile Packaging Manufacturer's council
- 5. Coordinate with AAMI/ISO and USP standards.
- 6. Investigate compliance statement with IoPP.

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