Data / Specification Sheet Task Group

IoPP Medical Device Packaging Technical Committee

Charter Statement

- The Data Sheet Task Group seeks to understand how specification sheets / data sheets are used by suppliers and users of medical packaging in order to determine if there are opportunities to increase the efficiency, accuracy or usefulness of this communication.

Objectives

- Determine how data sheets are currently used
- Determine if there are any needs going unfulfilled
- Determine if there are any improvements possible
- Propose data sheet improvements to IoPP Medical Packaging Technical Committee.

Membership

- Brett Baker
- Dhuanne Dodrill
- Nick Fotis
- Jennifer Neid
- John Ozcomert
- Geoff Pavey

Survey

- 8 question survey sent via e-mail to Medical Packaging Technical Committee
  - Determine how often used
  - For what purpose
  - If there is a high satisfaction level
  - Ways to improve the communication process

Survey data

- Responses received from 10 individuals (14% response rate)
- All used data sheets frequently – some daily or weekly
- How used?
  - Comparative performance
  - Specific physical properties
  - Develop specifications and MSDS documents
  - Comparison with competitor materials

Survey results

- What information do you use?
  - All standard physical properties
    - Thickness, yield, tensile, modulus % elongation, WVTR, O2TR, Porosity, Sterilization compatibility, Tear strength, Impact, haze, gloss, seal strength, composition.
  - Application and usage information

- What additional information do you need?
  - Accelerated aging and shelf life info
  - Flexcrack values, barrier properties
  - Nitrogen transmission rate for vacuum decay calculations
  - Lamination layer % thicknesses, adhesives used
  - Heat seal performance window
  - Material additives
  - Effect of time / heat / cold
  - Creep
  - FDA status
  - Melting points, softening points

How useful?

- 66% very useful
- 22% somewhat useful
- 12% not useful

- Of somewhat or not useful, usual responses were:
  - "Usually not enough information to help"
  - "Some are too arbitrary to use, some are marketing tools not Product data sheets. Proprietary information references are not useful at all"

How access? How valid

- Most through sales reps
- Some through Internet

- Everyone reported that the data sheets were reliable and representative of data found during later testing.
  - Some noted the biggest differences were in lab method or limited run sizes.

Ways to improve data sheets?

- Make available on the web (without password protection)
- Keep graphics to a minimum
- More application specific data: seal windows, forming characteristics (corner thickness for given aspect ratio
- “Get off the Marketing approach and re-focus data sheets for use of information and specification. “I don’t care about how glossy the paper is or how many times the logo appears – give me more relevant information with testing to support claims.”

Ways to improve (cont.)

- Standardize format for all products so you don’t have to look all over for the data
- List the exact test method used.
- Don’t list data for vendor-developed tests without a way to compare to standard test methods.
- Links to design guides and selected vendor publications.

Conclusions from survey

- Important, reliable and very frequently used form of communication between suppliers and users.
- Some opportunity for improvement
  - Technical data vs. marketing
  - Web based

Possible action plans

- Make a Generic Data Sheet as an example:
  - Order test properties
  - Test methods
  - Mean, Standard deviation and sample size
  - Arrange per 11607 organization
- Coordinate w/ FPA's Sterile Packaging Manufacturer's Council
- Coordinate with AAMI and USP standards
- Investigate "seal of compliance" statement for Data sheets complying with this Data Sheet Guidance document