



Medical

# Pall Medical Device Advisory Update January 5, 2005



# Speakers:

- Allan Ross, President
- Jerry Delgiacco, VP Product Engineering

# Objectives:

- Maintain active, two way communication
- Provide a situation update to all affected
- Communicate essential actions taken to determine root cause of hemolysis and planned actions in the coming weeks
- Hear concerns and answer questions
- Identify needs and devote additional customer service resources wherever necessary

# Brief Review of Events

- Initiated a limited voluntary recall of those lots of Pall BPF4 Filters where customers have experienced hemolysis in greater than 5% of the number of leukocyte reduced units produced
- Changed the labeled Instructions for Use for the Leukotrap® SC RC systems, limiting the use of these systems to collected units that are less than five days old
- Recall Forms/Information Resources provided through Pall Gateway on the Web  
[http://www.pall.com/medical\\_info.asp](http://www.pall.com/medical_info.asp)

# Update

- No adverse patient events reported
- No new validated significant hemolysis observances reported
- 0.027 incidence rate (27/100,000)
- Blood filtration is a complex business
- From time to time variability in blood processing occurs such as the events we're discussing, that cause much concern to everyone
- No supply issues/continuing to deliver replacement filtration products
- Processing recall forms

# Update

- Continue to actively investigate cause of hemolysis in red cells subject to filtration with specific lots of the Pall BPF4 filter.
- Ongoing collaboration and guidance from Industry
- Confident root cause will be determined
- We extend our sincerest gratitude for your continued support and patience

# Industry Task Force Convened

- Concluded that measures taken were sufficient to address acute issues that might have affected blood availability and safety
- Acknowledged that our industry lacks guidance on acceptable levels of hemolysis – referred to AABB Standing Committee for action
- Pall taking positive steps to assist the industry in defining acceptability, will bring greater focus on the issue of hemolysis occurring in the blood supply
- January Blood Safety and Availability Committee meeting topic

# Main Factors Under Review:

- Physiological
- Chemical
- Mechanical

# Assessment of Physiological Factors:

- Our extended investigation confirms that the only physiological factor involved in the scope of the problem is the age of the blood
- Control Study with unfiltered blood

# Assessment of Chemical Factors:

## Update on Testing

- MEM Cytotoxicity – Passed
- Hemolysis – Passed
- Endotoxin – Passed
- Systemic Injection – Due 1/10
- Intracutaneous Injection – Due 1/13
- IR SCAN – Due 1/17
- USP Physiochemical – Due 1/23
- Kligman Sensitization – Due 2/25

# Assessment of Mechanical Factors:

- ✓ Our current working hypothesis is that the increased hemolysis seen in the field is a result of a high mechanical shear stress on the red cells
- ✓ Preliminary test results on filter media, from an implicated filter lot, show an unexpected variation in a parameter associated with wettability of the media surface
- ✓ This variation can result in a reduction of effective area causing a localized increase in flow velocities, and exposes the blood to higher than normal shear rates

# Root Cause Analysis:

- Define statistical correlation between variable wetting / flow and implicated filter lots.
- A design of experiment is being conducted on our manufacturing process to create filter samples which may exhibit this out of spec condition.
- The implementation of additional process monitors to help gather data, and provide a higher level of quality assurance
- Evaluation of environmental factors

# “Progressive” Hemolysis:

We have a plan to address the concern that there is an increased rate of hemolysis over time

# Channels to Keep You Informed

- Utilizing Internet capabilities to the fullest
- Webcasts
- January BSAC Meeting
- Sales force and PAS Teams in field to deliver important updates
- Whitepaper & Technical Bulletin will be created and distributed as ongoing updates by various departments at Pall (engineering, manufacturing, Q/A)
- Validation Support and guideline tools (quick reference charts and other resources) will be developed to support customers
- Customer Service Hotline (800.645.6578)
- Spring Workshops

# Pall Medical

- Blood safety is our utmost priority
- We share a mutual interest in providing a high level of assurances of product quality for all involved in blood bank operations



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# Q & A