



PERFORMANCE. POWER. SPEED.

BARDA Industry Days– 10/30/2018



- Silverlon is an antimicrobial dressing that can be used for up to 7 days for the following indications:
 - Partial and full thickness wounds including traumatic and surgical wounds (donor and graft sites, incisions)
 - 1st and 2nd degree burns
 - Dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers)
 - Vascular access or peripheral IV sites
 - Orthopedic external pin sites
 - Wound drain sites
- Multiple independent peer review published studies on the use of Silverlon
- Easy to use
- Stable, light weight and easy to store
- Used daily in hospitals throughout the US and internationally
- Commercially available for over 15 years
- 5 year shelf life



- 2011 Argentum attended the BARDA Industry Days for the 1st time
- Early 2012 submitted the first proposal to BARDA
- Mid 2012 received feedback and resubmitted our proposal
- Dec. 2012 met with BARDA SME's for in-depth feedback
- April of 2013 resubmitted proposal
- September 2013 awarded a \$16.5 million contract to fund the initial studies for repurposing of the Silverlon Burn and Trauma dressing for use in mass casualty incidents involving radiation and vapor sulfur mustard exposure.
- November 2015 presented the results of the vapor sulfur mustard studies through the IPR process
- December 2015 Argentum was awarded the contract to perform the GLP studies for a vapor sulfur mustard indication
- October 2018 submitted a De Novo 510k to the FDA
- March 2018 submitted a proposal to open BAA for burn medical countermeasures for cutaneous radiation injury (CRI)
- September 2018 Argentum was awarded an \$8.4 million to repurpose Silverlon Burn dressing for radiation injuries of the skin.

- How do you take a cleared device and “repurpose” it for MCM indications?
 - Listen to BARDA’s feedback!
 - Ask a lot of questions
 - Hire the best SME’s
 - Work with CRO’s that have BARDA experience
 - Hire FDA consultants / law firm with BARDA experience
 - Use the FDA pre-sub process early and often
 - The FDA as been very cooperative in providing feedback
 - Expect a large number of FDA SME’s to participate
 - Expect multiple pre-sub meetings
 - Be patient much of this work has never been done before