## **AMxTek LLC**

## Kerlix™ AMD



Kerlix<sup>™</sup> AMD - Antimicrobial Gauze Wound Dressing K990530

> Antimicrobial: Polyhexamethylene Biguanide [PHMB]; a polymeric biguanide

## As V.P. of R&D, Responsibilities and Contributions included:

- o Technology Due Diligence: Identification and sourcing of antimicrobial technology
- Product Performance: Antimicrobial efficacy testing via in-vitro assays; in-situ [animal] studies; and ex-vivo human effectiveness and sensitization trials; all in support of FDA Pre-market Notification
- PHMB Formulation Optimization: Optimized antimicrobial effectiveness vs. cytotoxicity
- Manufacturing Process Development: Managed process development effort for binding PHMB to cellulose [i.e. cotton]
- Kerlix AMD 'White Papers' 1-3: FDA and Marketing support materials re: new product launch package