

# THE "BIOBURDEN" OF PROOF

Are reusable garments putting your process at risk?

## CONTAMINATION HAPPENS

Personal garments are the  
**#1 CAUSE FOR ALERTS AND ACTIONS<sup>†</sup>**



† After the floor

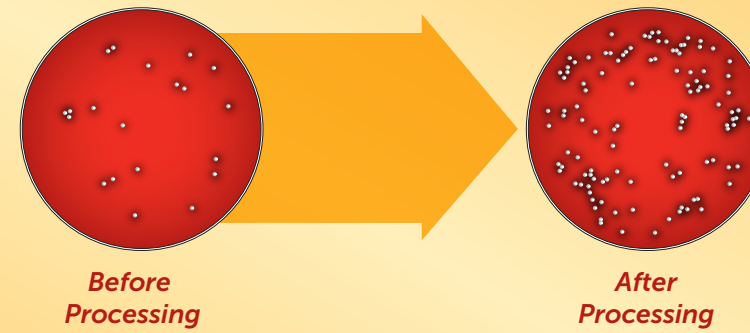
## PEOPLE ARE THE #1 SOURCE OF CONTAMINATION

**1/2** THE TIME PEOPLE are the root cause for microbial contamination in the cleanroom<sup>1</sup>



## BARRIER USED TO PROTECT THE PROCESS IS FAILING

**100%** of reusable gowns tested **SHOWED A DECLINE** in BFE after processing.<sup>2</sup>

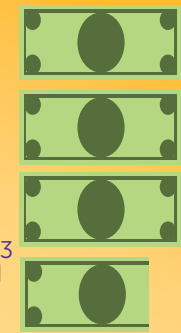


Reusable gowns **DROP IN BFE OF OVER 25%** after laundering and sterilization.<sup>2</sup>

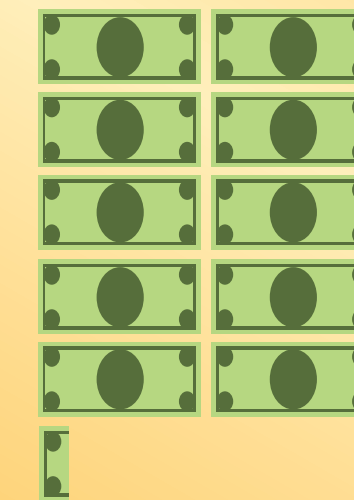


## YOU CAN'T AFFORD THE RISK

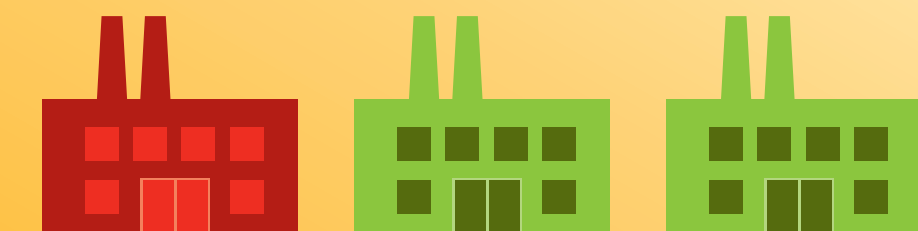
**\$375 MILLION** spent to address a single FDA contamination concern<sup>3</sup>



**\$1.1 BILLION** lost in global sales due to production shutdown<sup>4</sup>



**1/3** OF INDUSTRY'S MANUFACTURING CAPACITY IS OFF-LINE because of quality issues<sup>5</sup>



Sources:  
1. PDA Midwest Meeting 032510  
2. KC Test Study and CAP review approved CAP WRS12-308  
3. <http://www.fiercepharmamanufacturing.com/story/hospira-manufacturing-problems-arise-inopportune-time/2013-02-28>  
4. <http://www.forbes.com/sites/edsilverman/2012/01/10/254/>  
5. [http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html?pagewanted=all&\\_r=16](http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html?pagewanted=all&_r=16)

It's time to rethink your choice in garments.