Office of Technology Development

Risk & Regulatory Working Group

Exoskeleton - G Meeting
Marriott Gateway
June 28 and 29, 2017
Where we Started

Risks

- Who is liable for user injuries and equipment failures; manufacturer, user, other?
- How is fitness-for-service assessed?
- What are the requirements for basic knowledge, proficiency, and refresher training established?
- Should the use of exoskeletons be a personal choice?
Need Common Terminology

Concerned with Safety and Insurance

Existing Standards

- Robotic Standards
- ISO 13482 – Robots and Robotic Development - Safety Requirements for Personal Care Robotics
- ANSI 15066
- Collaborative Robot Standards
- UL 227 Electric & Fire standard
- There are no ergonomic standards

However, No consensus standards
Exoskeletons are TRL 6 Today, but Need to be TRL 8

FDA Approves Medical Devices & OSHA will approve Industrial Exoskeleton Devices

Acceptable Risks a concern, for example at Harley Davidson, a worker requires a hoist to lift a motorcycle frame of 70#, an exoskeleton might be able to eliminate the use of the hoist and change time and money

However, injury reports from companies are protected and secretive (not accessible)

We need to understand safety, including PPEs

For example, is an exoskeleton valued as an automobile or hammer (tool) for liability concerns?

Today, No compilation of Knowledge on Exoskeletons (No Data)
Issues Needing Answers

- What are the long-term effects to the user?
- What essential muscle groups should we measure with sensors?
- Exoskeletons require the “Human Subject Research Protocol”
- We Do Not Know The Long Term Effects of Exoskeletons
- Need Training Protocols – long term activity
- IRB needs extensive testing and being transparent
Barriers to Entry

- Need sharing mechanism to collect data
- Broad-use not regular

1) Corporate Barriers

2) Regulatory Barriers

Standards (Reportable Failures)
- RESNA
- ASTM

Helps Insurance

Office of Environmental Management