



# Assurance Cases

Paul L. Jones  
OSEL/CDRH/FDA

# Assurance Cases

Assurance case pilot program launched

Assurance case documentation submitted

Observations:

- Table format
- Graph format



# Assurance Cases

## Claim (s)

- Elements of guidance are met
- Device is acceptably safe

# Assurance Cases

## Lessons being learned

- Be clear what claims are desired
  - What are the properties of a system that need to be addressed to convince a regulator that the product is safe?
  - How does one know that a hazard analysis is complete?
- \* time spent on risk estimation is a waste



# Assurance Cases

Possible assurance case pattern

- Hazardous situation
- Cause (s)
- Control measure (s)
- Acceptance criteria
- Verify control measures & their effectiveness
- Validate control measures & their effectiveness

# Assurance Cases

## Conclusion

Need to identify critical system properties and the means to demonstrate that these properties are satisfied.