



THE SOLABS USER GROUP MEETING
2023 EDITION



Regulations vs Guidances

- Compliance with regulations is mandatory
- Inspections are chief method of obtaining evidence of compliance
- Escalating range of possible FDA enforcement actions include
 - Exit discussions
 - Form 483's
 - Warning letters
 - Consent decrees, seizures, and sanctions
 - Referrals to Justice Department for criminal prosecution
 - Debarment
- Guidance for Industry documents, ICH Q's, ISO's
understanding and following regulations



TYO BIOTECHNOLOGY CONSULTING





Kinetic Energy

Speed

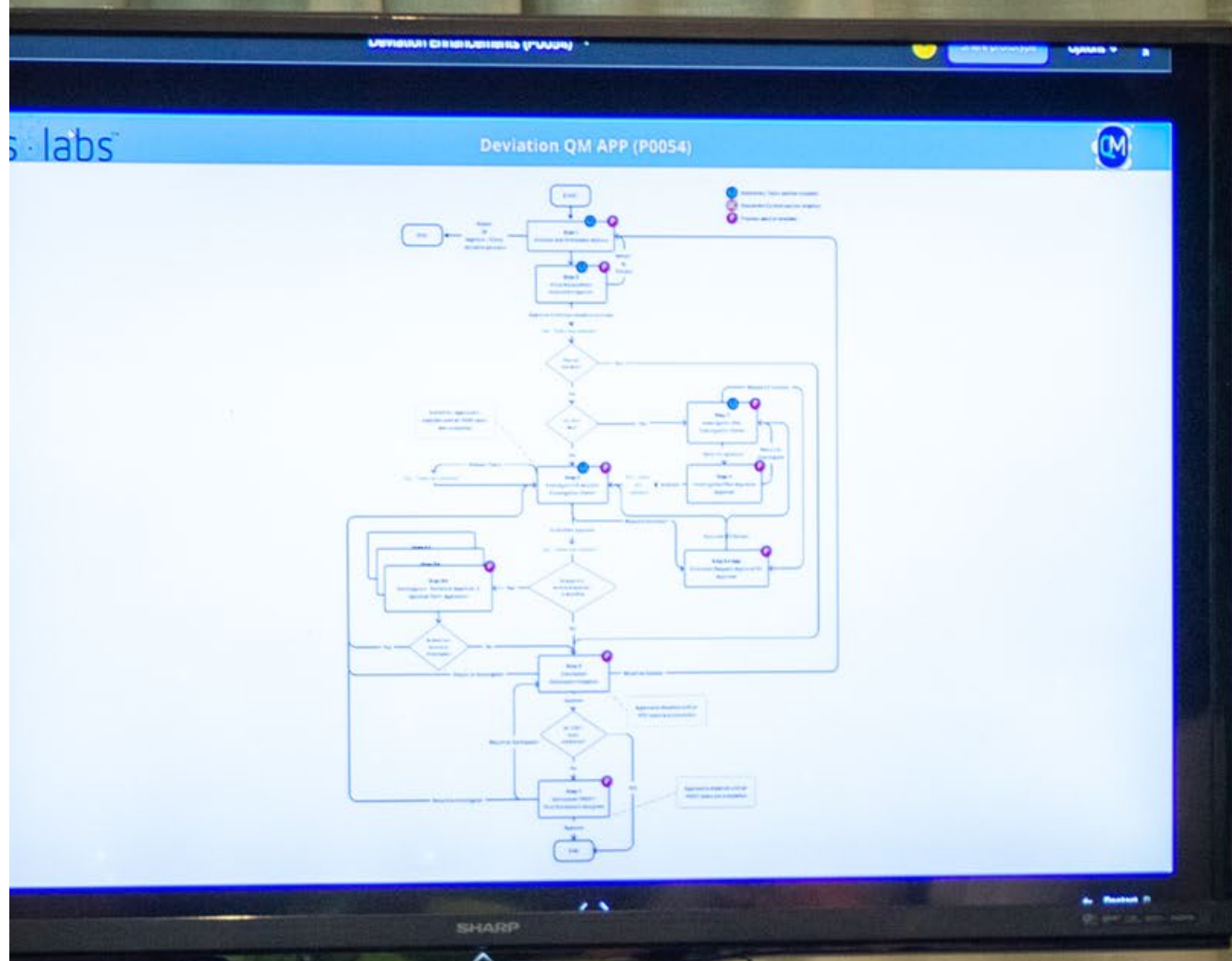
- Control
- Decision
- Action



SKILL PAD®









Automated Support Intervention Process

Goals

- Significantly lower **impact** of intervention / updates on client daily operation
 - **Target: 1h to 1h30** regardless of the intervention time
- Raise the **level of control** on changes
 - **More information** provided on impacted files
 - **Record of each intervention**
 - **Audit trails** of system configuration
- **Will eventually be part of the SASC**

UGM





Online Assessment Innovaderm Use Case



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SEE YOU NEXT YEAR!!!!