

Compliance Data Exchange (CDX)

**Driving Compliance Excellence: Uniting
Departments for Sustainable Success**

Monika E. Kotkowska, Regulatory Product Compliance Expert

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Speaker Introduction

Monika Ewelina Kotkowska

Business Consultant / Regulatory Product Compliance Expert
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- Engineering and Master Degrees in Chemistry and Polymers
- Conflict Minerals Program, Chemical Compliance, Post Market Surveillance, IVDR, Regulatory Affairs, EHS, ISO 14001, ISO 45001, ESG
- Medical Devices, Life Science, Biotechnology, IVD, Aerospace & Defense, Automotive, Electronics and others
- Active member of IAEG trade association WG9
- Past member of MedTech Europe trade association
- Certified Project Manager (Agile and Prince2) and Scrum Master

Webinar Housekeeping



This session is being recorded



The recording will be shared on the CDx Website



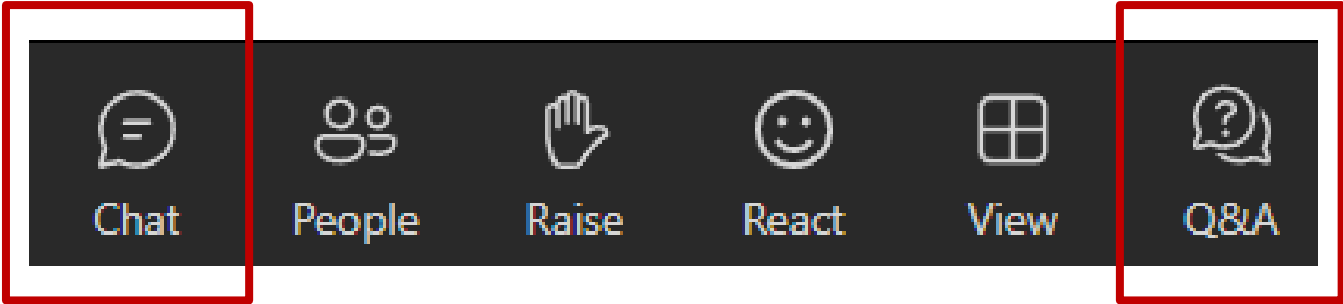
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Chat to share with others



Q&A to post questions



Webinar Agenda



All Stakeholders



Quality Management (QA)



Procurement

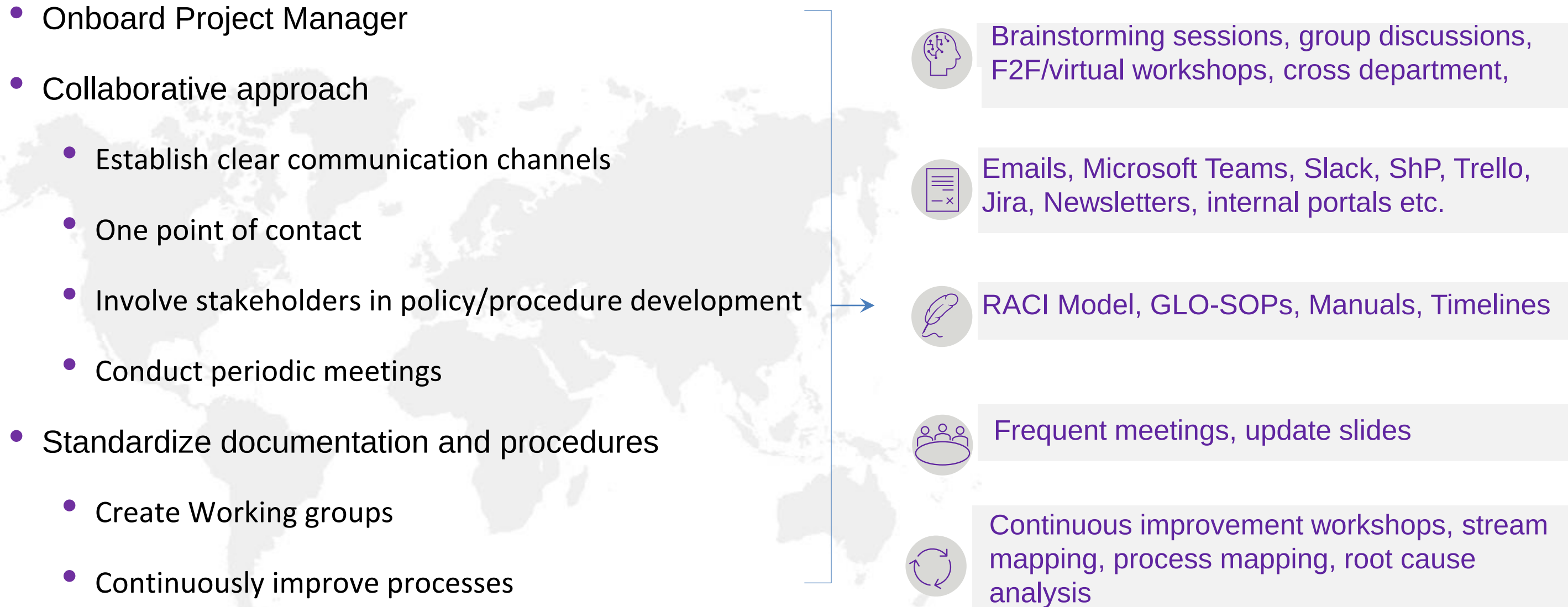


Environmental, Health and Safety (EHS) and
Regulatory Affairs (RA)



Design Engineering

Building a Culture of Compliance: Internal Stakeholders



Effective Engagement for Compliance: Involving Internal Stakeholders in Policy Development and Beyond

Building a Culture of Compliance: Internal Stakeholders

- Develop training and awareness programs
 - Simplify complex compliance information
- Measure and report on compliance performance
- Foster a culture of compliance
 - Recognition and rewards
- Provide ongoing support
 - Seek feedback and address concerns



Training on procedures, trainings on platform, scenarios, avoid jargon



Develop metrics and key performance indicators (KPIs) to track compliance performance



Recognition and rewards, recognition platform, Yammer, email, newsletter, townhall



Accessible documentation, FAQs, helpdesk, point of contact, frequently meeting

Measuring Success through Engagement: Enhancing Compliance with Internal Stakeholder Participation

Procurement

1. Share resource (additional intern, FTE, Project Manager)
2. Develop training and awareness programs
3. Develop consistency in process and language,
4. Clear R&R, RACI
5. Develop a risk-based program that accounts for both teams
6. Escalation process
7. Measure and report on compliance performance
8. Recognition and rewards



Design Engineering

1. Develop training and awareness programs
2. Develop consistency in process and language
3. Clear R&R, RACI model
4. Proactive approach
5. Limited involvement in the design process
6. Success story



Quality

1. Involve in the beginning of the process
2. Avoid conflict in priorities
3. Overlapping responsibilities (R&R, RACI)
4. Establish document control processes
5. Involvement in policy and procedures development

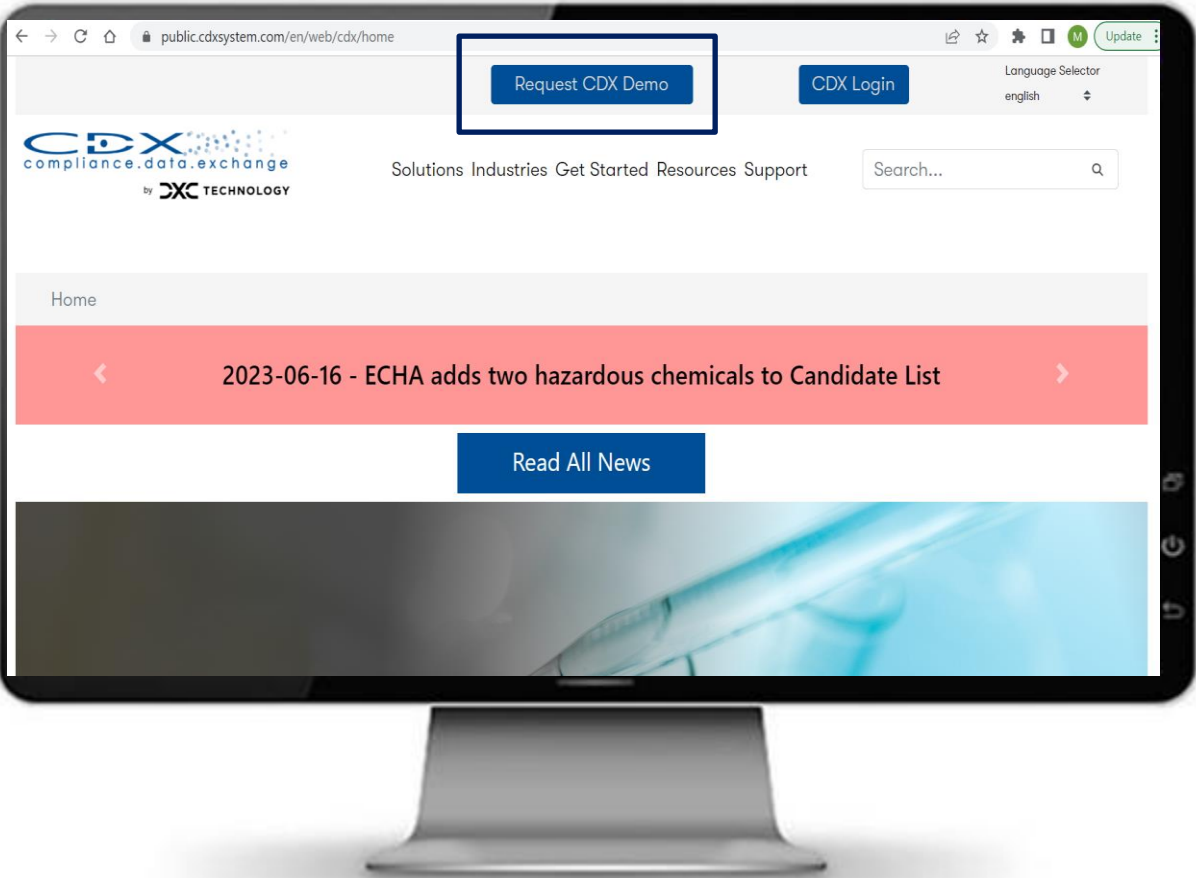


Environmental, Health and Safety (EHS) & Regulatory Affairs (RA)

1. Avoid overlapping responsibilities (R&R, RACI, workshop, roadmap)
2. Measure and report on compliance performance
3. Provide compliance training and education
4. Involvement in compliance planning
5. Involvement in policy and procedures development



Empowering Internal Stakeholders through CDX



Supplier evaluation and selection
Mitigating supply chain risks



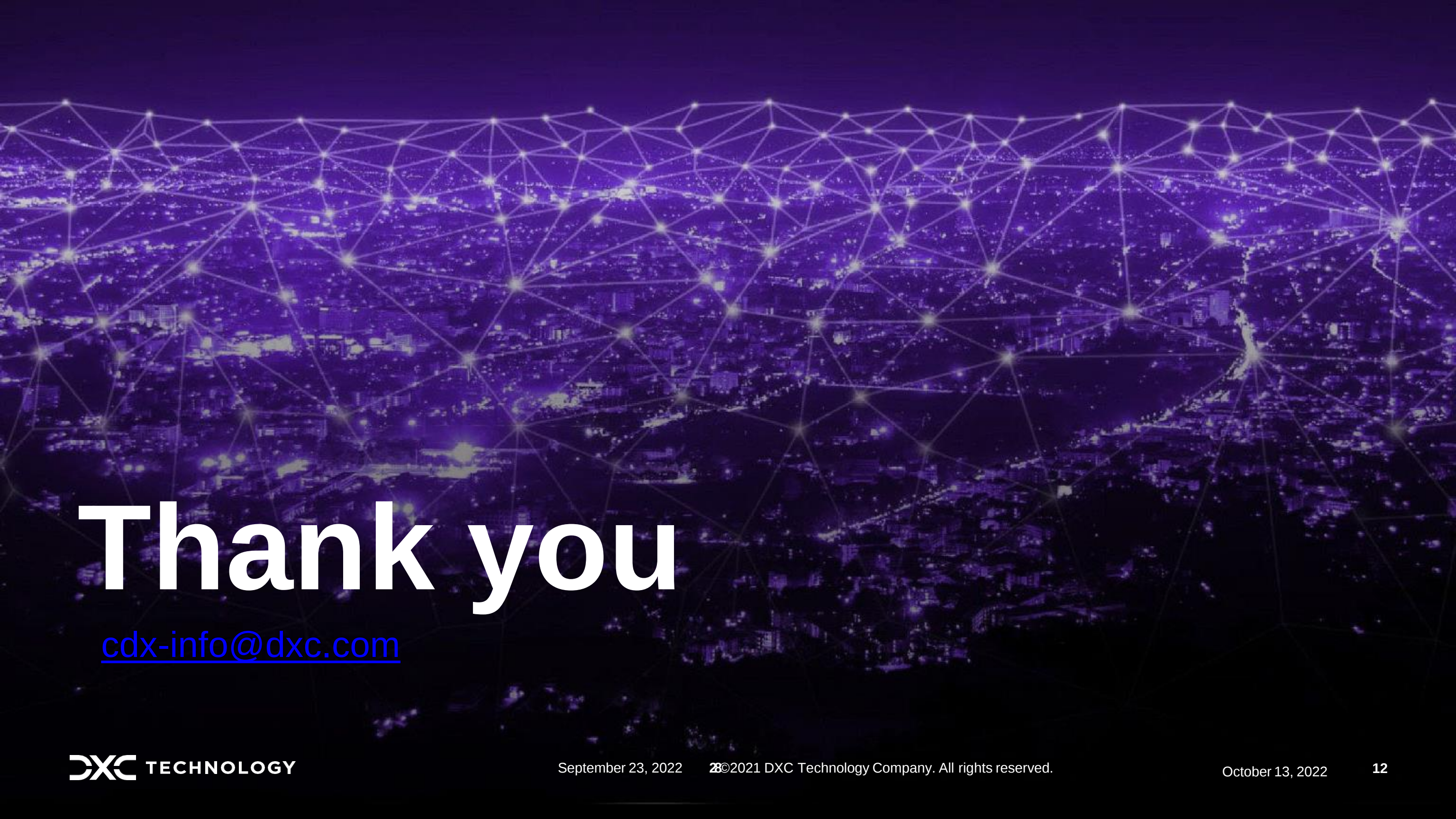
Informed product design
Innovation with compliance in mind



Improved product and process quality
Real-time monitoring and reporting



Effective compliance management
Enhanced safety measures



Thank you

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Questions and answers

