Improve Medical Device Quality Using Defect Images – *introducing defectlibrary.com*

Presented by Jerry Xiao

RdQCC LLC

CQE, CQA, CSSBB, CRE

jxiao@rdpdm.com

www.defectLibrary.com

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CERTIFICATE OF APPRECIATION

AWARDED TO

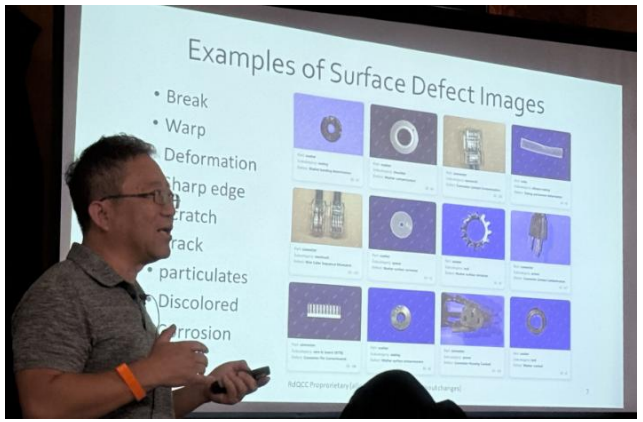
Jerry Xiao

For contributing to member value for
American Society for Quality, Orange Empire section 0701
for your presentation on 13th January **2026,**
at our Monthly Section Meeting

"Using AI-Powered Application to Analyze Medical Device Risk from Defect Images"

Awarded this 2026 calendar year

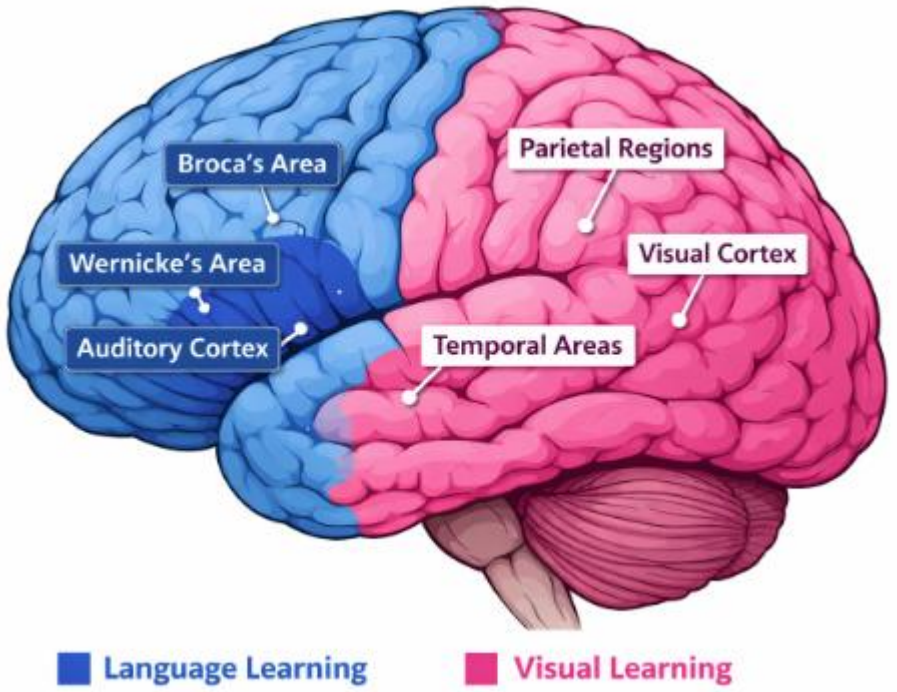
Nagesh Malhotra, ASQ 0701 Section Treasurer
Value of this certificate is **One (1)** Recertification Unit



Background

- Total neurons in human brain: 86 billions

Dimension	Language-based learning	Visual-based learning
Primary entry neurons	120–210M	330–490M
% of total brain	0.15–0.25%	0.4–0.6%
Processing style	Sequential	Parallel
Pattern sensitivity	Low	Very high
Anomaly detection	Weak	Strong
Memory durability	Medium	High
Emotional activation	Low	Moderate–High



Agenda

- ❑ Product part defects, impacts, and challenges
- ❑ Examples: surface defect images
- ❑ Examples: defect images-based risk assessment
- ❑ Introduce to defectlibrary.com
- ❑ Workshop
- ❑ QAs

Overview Medical Device Problem

- Medical device problem
  Any malfunction, deterioration of function, failure of medical devices that have occurred in pre- or post- market (e.g. clinical studies, clinical evaluation or post-market surveillance).
- IMDRF structure of medical device problems (2025)
  Hierarchical (3 levels), problem terms & codes(**491**), traceable(unique ID), and scopes.
- Harmonized with FDA terms and NCI terms
- Standardize term lists of defects and failure modes

Level 1 Term	Level 2 Term	Level 3 Term	Code	Definition	N
Material Integrity Problem	Material Deformation		A0406	Problem associated with an undesired material change in shape or property caused by external forces.	
		Deformation Due to Compressive Stress	A040601	Problem associated with an undesired bulge, bend, bow, kink, or wavy condition observed in the device material resulting from compressive stresses.	
		Dent in Material	A040602	Problem associated with a undesired change in shape, characterized by the presence of a slight hollow (dent) in the device surface.	
		Failure to Fold	A040603	Problem associated with an undesired material change in physical property, characterized by failure to fold.	
		Failure to Unfold or Unwrap	A040604	Problem associated with the comprising materials' deformation in that device fails to open its wrapping or open/extend in a certain manner i.e. balloon or lens.	
		Material Frayed	A040605	Problem associated with the comprising materials having damaged edges.	
		Material Invagination	A040606	Problem associated with an undesired material change in shape, characterized by the infolding of one part within another part of a structure.	
		Material Too Rigid or Stiff	A040607	Problem associated with undesired rigidity of device material (resisting deformation in response to an applied force).	
		Material Too Soft/Flexible	A040608	Problem associated with any device material that results in the material's inability to maintain the desired shape or support function.	

Impact of Product Defects

Product defects significantly affect cost, compliance, and patient safety

- Direct Defect Costs

  Average defect rate (0.1-5%); scrap & rework (3-10%); inspection, testing, and containment (2-5%); total defect related costs in the global medical device industry are approximately USD 120 billion per year.

- Product Recalls in USA (2023)

  For consumer products, 322 recall events, impacting approximately 135.2 million units; for medical devices, 975 recall events affecting 283.44 million units *(source: PR Newswire)*

- Patient Safety in USA (2023)

  Approximately 12.7 million individuals were treated in emergency departments for injuries and over 700 deaths due to product incidents (*Source: Stein Whatley*)

- Regulatory violation

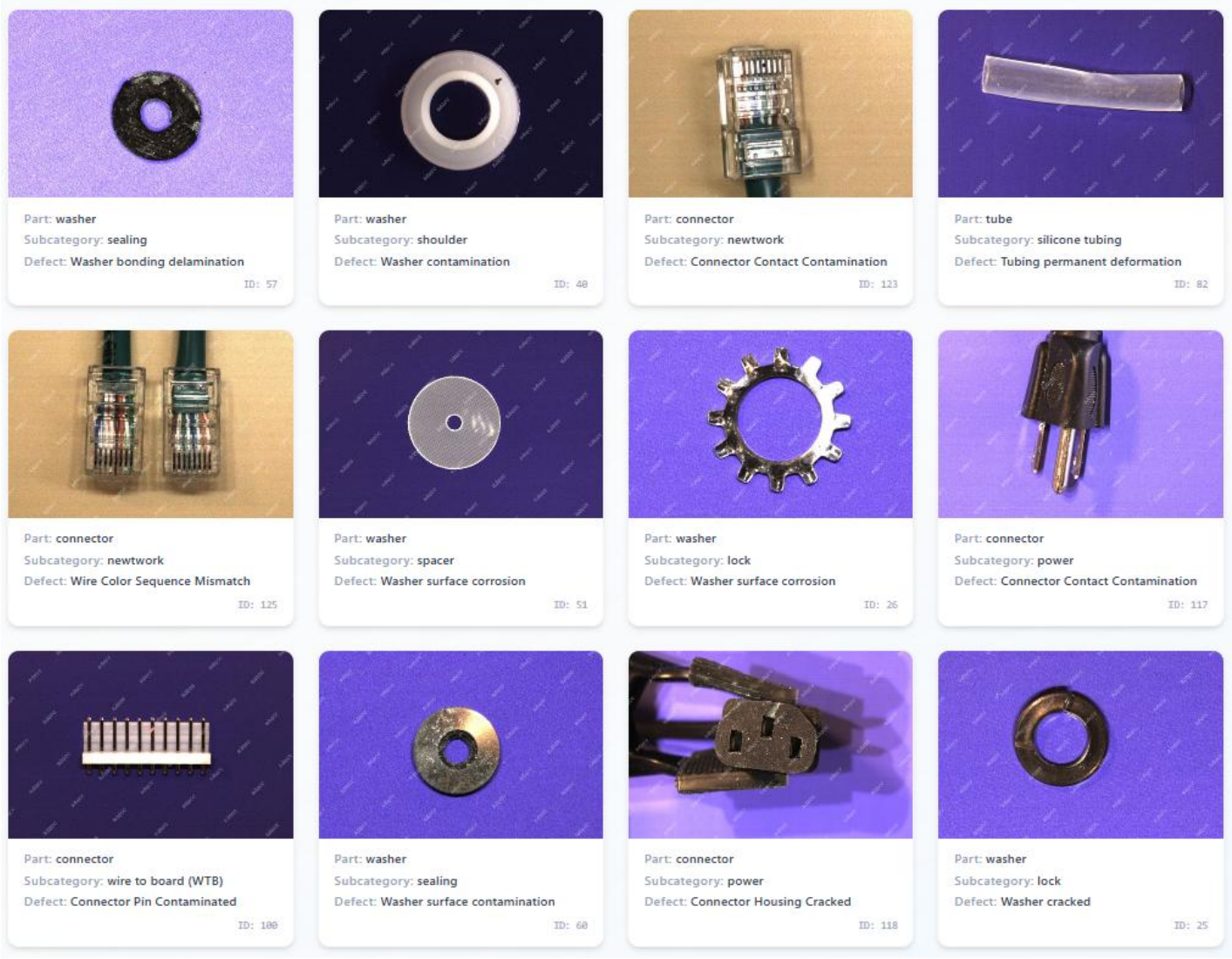
  FDA 820.90: each manufacturer shall establish and maintain procedures to identify, document, evaluate, segregate and dispose of nonconforming product.

Challenges in Language based Risk Assessment

- Inconsistent Defect Description and Interpretation
  Due to language limitations, inspectors may describe the same defect differently, and readers may interpret identical descriptions inconsistently. Defect images help eliminate ambiguity by providing a shared visual reference.
- Incorrect Root Cause Analysis
  Poor defect description and limited investigations can lead to incorrect root cause identification. Defect images provide critical visual inputs to support accurate root cause identification.
- Ineffective Defect Risk Analysis
  Text-only defect description slow cross-functional discussions and introduce bias. Defect images communicate the issue immediately and support objective risk assessment.
- Incorrect Corrective Actions
  Recurrent defects are often observed over long periods due to ineffective corrective actions. Defect images help ensure corrective actions by improving root cause analysis and defect risk analysis.

Examples of Surface Defect Images

- Break
- Warp
- Deformation
- Sharp edge
- Scratch
- Crack
- particulates
- Discolored
- Corrosion



Defect image-based Risk Assessment

- Failure mode
- Failure cause
- Hazard
- Hazardous situation
- Harm
- Risk level
- Risk control measures

connector newtwork

Connector Insulation Damage

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AI-Powered Analysis

Preview comprehensive defect analysis data

Device Analysis
Material properties, medical applications, manufacturing processes, and industry standards.
Preview

Defect Management
Failure modes, acceptance criteria, root causes, and mitigation strategies.
Preview

Risk Assessment
Hazard identification, severity levels, and device-specific risk analysis.
Preview

Summary: Benefit of Using Defect Images

- Provide immediate visual evidence

  Instead of long descriptions or subjective interpretations, everyone is looking at the same reality. Leads to faster, more consistent, and higher quality risk assessment.
- Understand part risks before using them

  Defect images turn abstract risk into tangible evidence, enabling smart part selection and stronger design choices from the very beginning.
- Support inherent safe design

  During the early stages of product development, engineers can use defect images to translate those lessons into product requirements.
- Essential for Training AI Models

  AI can not learn defects or risks from text alone. Defect images allows AI to recognize patterns, assess risks, and eventually support automated quality control.

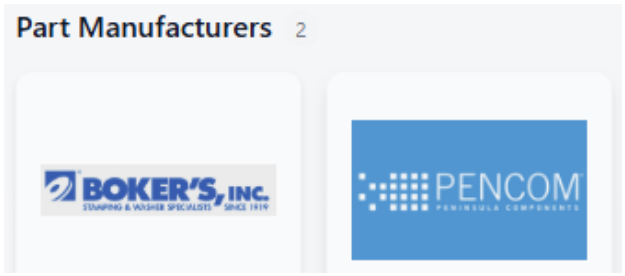
Introduce defectlibrary.com

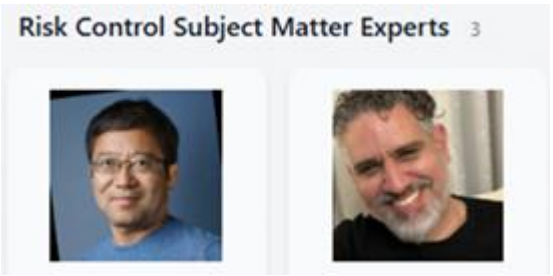
DefectLibrary is a collaboration platform for building, collecting, and sharing:

- Product defect images
- Manufacturing nonconformance videos
- Defect risk analysis insights and lesson learned

User scopes:

- Students study engineering to participate in hands on projects
- Product design engineer, process engineer, or quality engineer
- Part manufacturers who commit to customer expectation
- Measurement system and inspection system providers
- AI companies who train bimodal models on quality





Major Features of defectlibrary.com

- **Defect Image management:** easily search defect images per part category, subcategory, defect type; users may post a request enabling contributors to supply content.
- **Defect Risk Assessment & Product Risk Documentation:** in-depth risk assessment on each defect image; users may create new assessment when none are available; if BOMs is available, the platform will generate a Design FMEA report.
- **Royalties, fees, and compensation:** you own rights. When your content is downloaded, you earn a royalty payment.
- **Risk Control SMEs**: host a community of risk-control SMEs, deep knowledge of medical device use scenarios, provide specialized risk management support for specific parts, failure modes, risks, and device applications.

Join as a Contributor

- Who can be a Contributor?

  Anyone can become a **contributor** through joining as a member.
- Contributor workflow

  Upload your defect images and videos
  Provide defect-related risk analysis and insights (option)
  Earn royalties, fees, and other compensation
- Contributor 1: Product developer

  While developing a new product at my garage, I discovered some unique defects and shared the images, disposition, and risk assessments on Defectlibrary.com
- Contributor 2: Part manufacturer

  We post our defect images to the platform in order to collect impact of our potential customers informed by expert risk assessment.
- Contributor 3: Quality engineer

  I visit defectlibrary to identify defect images without risk assessments and contribute risk assessments within my expertise.

Join as a Subject Matter Expert (SME)

- Who can be a SME?

  Design quality, manufacturing quality, supply quality, risk management engineers with hands-on industrial experience (e.g. standards, defect inspection system, risk controls).
- Contributor workflow

  Review defect images and nonconforming videos; identify applicable use scenarios; perform risk assessment; provide feedback on risk assessment from others.
- SME 1: Familiar with Material Integrity Problem

  Break, crack, degraded, flaked, material deformation, discolored, perforation, split, flaked, peeled, worn, dent, frayed, material invagination, twisted, bent, melted, etc.
- SME 2: Familiar with Mechanical Problem

  Detachment, leak, dislodged, dislocated, ejection, jam, misalignment, noise, sticking, structure problem, retraction problem, unintended movement, slipped, vibration, etc.
- SME 3: Familiar with Contamination Problem

  contamination, residue, particulates, coagulation, biocompatibility, cross reactivity, precipitate, chemical reaction, corrosion, etc.

Workshop: Search Defect Images

Case 1: Search by Part Type

- Objective: find defect images related to washers
- Keyword used/search input: Washer

Case 2: Search by Defect Type

- Objective: find images of crack defects across all parts
- Keyword used/search input: Crack

Case 3: Search by Part + Defect

- Objective: find defect images of washer cracked
- Keywords used/search input: washer crack

Milestones & Roadmap

Phase 1: Medical Devices

- Target 300+ medical device components (IMDRF)
- Collect 30,000+ high quality defect images including associated risk assessment aligned with medical device application.

Phase 2: Pharmaceuticals

- Target 300+ pharmaceutical components
- Collect 30,000+ high quality defect images including associated risk assessment aligned with pharmaceutical application.

Phase 3: Consumer Products

- Target 2,000+ consumer product components
- Collect 200,000+ high-quality defect images focus on large-scale defect pattern analysis.

Phase X: Construction, nature……

Contact Info and Q&A

RdQCC LLC

www.rdqcc.com

Email: jxiao@rdpdm.com

Phone: 760-681 9887