TÜV SÜD America

Choose certainty. Add value.

Effective Strategies for Complaint Handling

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TÜV SÜD in numbers: Growing from strength to strength

1	One-stop technical solution provider
150	years of experience
800	locations worldwide
2,060	million Euro in sales revenue 2014
22,000	employees worldwide

Note: Figures have been rounded off.

Technical expertise & broad industry knowledge

Testing & product certification

Chemical, physical, mechanical, electrical and environmental testing and product certification.

Inspection

Product, system, building, plant and infrastructure inspection.

Auditing & system certification

Audits system certification in a variety of fields including quality, safety, energy, IT security, social compliance and environment.

Knowledge services

Safety, quality, risk, environmental protection and regulatory advisory.

Training

Training in work safety, technical skills, management systems and executive programs.

Our asset. Your advantage.

TÜV SÜD: A brand synonymous with quality and safety. Our certification marks certificates are excellent marketing tools for our customers. Our test reports provide customers with the confidence to market their products' safety, quality and sustainability attributes. Our personnel certificates provide our customers with greater market opportunity.

> 500,000 product certificates

> 46,000 system certificates

> 20,000 personnel certificates
> 160,000 participants

Global expertise. Local experience.

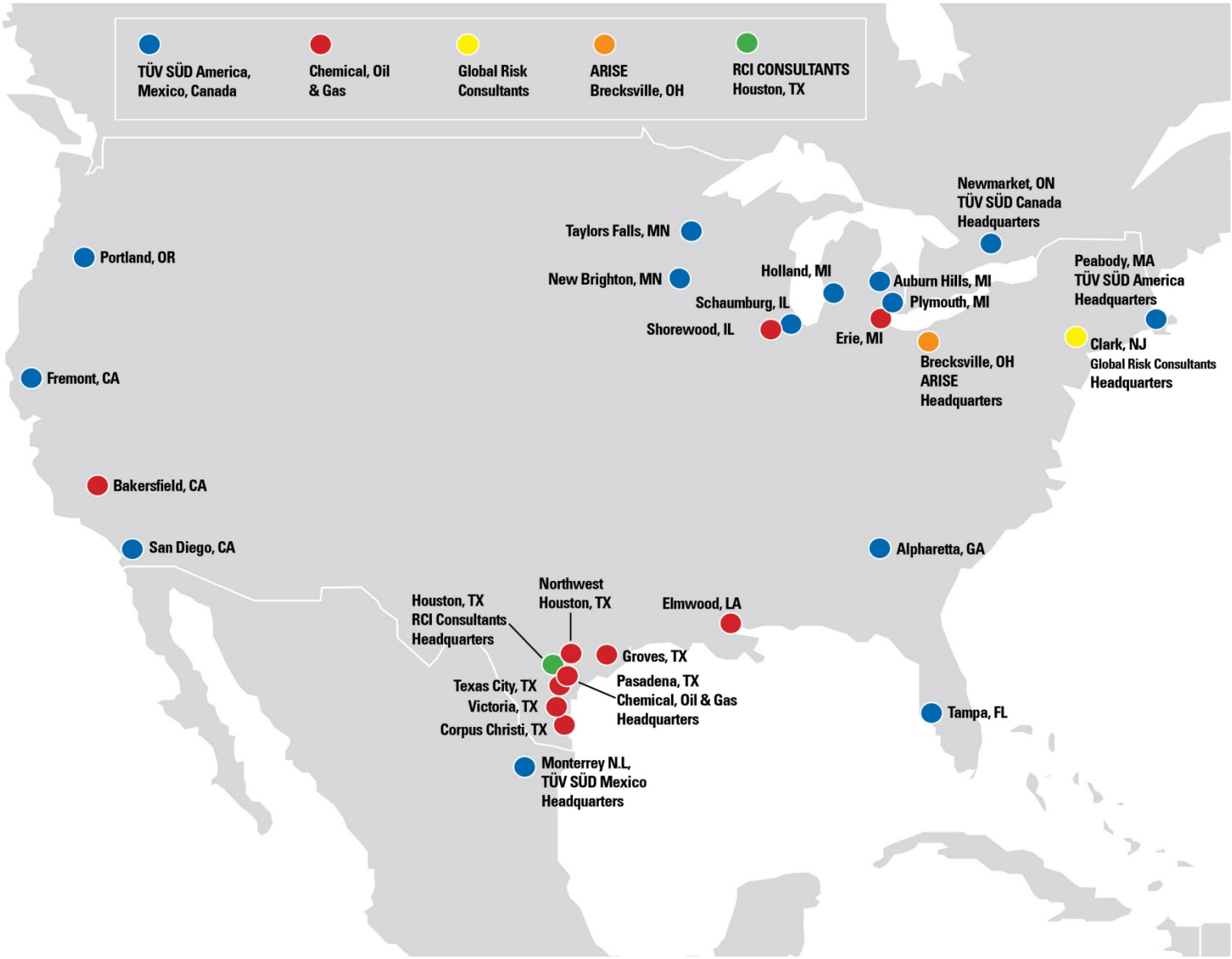
Legend:

- Countries with TÜV SÜD offices
- Regional headquarters

Note: Figures have been rounded off.

GERMANY	INTERNATIONAL
Euro 1,240 mio 10,400 staff	Euro 820 mio 10,800 staff

TÜV SÜD America Locations



TÜV SÜD America Inc.

- TÜV SÜD America Inc., founded in 1987, is the North American subsidiary of TÜV SÜD AG.

- TÜV SÜD America Inc. provides complete services through its divisions:
  - Product Service
  - Management Service
  - Industry Service
  - Chemical, Oil and Gas
  - Global Risk Consultants

A Compliance Headache?

OR

The Foundation for Continuous Improvement and Risk Reduction?

Discussion Topics for Today's *Quality Digest* Webinar

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2. Basic Definitions & Regulatory Requirements
3. Practical Steps for Efficient Complaint Management
4. Summary of Best Practices
   Tips & Tricks
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Getting Into a Risk Mitigation State of Mind

- Product Improvement
- Compliance Assurance Risk
- Corrective and Preventive Action
- **Complaint Management**
- Product Liability Risk
- Safety Risk Patients and Users
- Business Risk

Benefits of an Effective Complaint and Service Management System

- Assure highest possible levels of product safety and performance;
- Facilitate identification and implementation of product improvements;
- Inspire employees and customers to report product performance issues and adverse events promptly;
- Establish a system that effectively *and* efficiently meets the requirements of customers, regulators and other stakeholders;
- Minimize exposure to product liability lawsuits; and
- Reduce the Cost of Poor Quality.

Compliant Management is an Essential Risk Management Tool!

Reducing *Patient / User Safety Risk*

- Assess All Sources of Safety Inputs
  - ✓ Complaints and Service Experience
  - ✓ Adverse events – Death and Serious Injury
  - ✓ Clinical inquiries
  - ✓ Published literature
  - ✓ Conference proceedings
- Compare Severity and Rate of Incidence to Current Risk Assessment
- Consider Revising Risk Levels Using Established Procedures
- Ongoing Review of Risk-Based Actions During Management Reviews
- Rapid Response to Sentinel Events – *Risk-Based Reaction Plan*

Reducing *Business Risk*

- Loss of Revenue
  - ✓ You are off the market because of a shipment hold or a recall with no corrective action in sight; sales volume plummets.
- Cost of Poor Quality (COPQ)
  - ✓ COPQ erodes profit as problems ignored early on now lead to scrap, rework, reimbursement for returns and field actions.
- Unrecognized Problems at Suppliers and Subcontractors
  - ✓ Delays in initiating root cause analyses overlooks these sources of problems that can ultimately erode profits.

Reducing *Business Risk*

- Loss of Market Share
  - ✓ Competitor jumps in to fill the void while your company is off the market because of a recall with no products in the pipeline.
- Erosion of Customer Confidence
  - ✓ After successive recalls, customers begin to doubt the safety, integrity and reliability of your products.
- Deterioration of Employee Morale – Retention Issues
  - ✓ Employees become disheartened by the stigma of repeated product failures and recalls.
  - ✓ More time spent doing root cause analyses and corrective actions than designing exciting new products.

Reducing *Business Risk*

- Use Complaints as an Early Alert to Sources of Business Interruption
  - ✓ Processes are Out of Control
  - ✓ Supplier Components or Subassemblies are Failing to Meet Specifications
  - ✓ Contract Manufactured Devices or Services are Not Meeting Specifications
  - ✓ There are Failure Modes That Pose a Risk to Health
  - ✓ Unanticipated Service Issues are Emerging:
    - o Parts Quality is Deteriorating
    - o Cost Increases Could Compromise Service Delivery
    - o Skills Training Is Needed for New Versions of Products
    - o There are Insufficient Resources to Handle Field Service Issues.

Reducing *Business Risk*

- Predictive Tools
  - ✓ Use DFMEA, FMECA, PFMEA down to Supplier Level to Predict Critical Outputs
  - ✓ Establish Appropriate Risk Mitigation Steps
    - o Verification & Validation
    - o Process Controls
    - o Testing as appropriate
  - ✓ Establish Sensitive Triggers Based on Criticality to Alert at Low Cumulative Number of Complaints
  - ✓ Predict Critical Failure Interruptions Such As:
    - o Field Corrections and Removals
    - o Line Stoppages
    - o Customer Conversion to Competitive Product

Reducing *Product Liability Risk*

- Establish, Maintain and Follow Effective Procedures to Demonstrate Due Diligence in Investigating Complaints
  - ✓ Complaint Handling
  - ✓ Adverse Event Investigation and Reporting
  - ✓ Failure Investigation
  - ✓ Root Cause Analysis
  - ✓ Corrective and Preventive Action
- React Quickly and Consistently to Adverse Event Reports
  - ✓ Use Standardized Death and Injury Investigation Questionnaires
  - ✓ Fully and Clearly Document the Association Between the Event and the Product
  - ✓ Be Cautious Regarding Attributing Deaths and Serious Injuries to User Error (Was it Actually Design? Labeling? Training? Malfunction? Manufacture? Servicing? Recent Corrective Action?)

Reducing *Product Liability Risk*

- Comply with Mandatory Incident Reporting Requirements Promptly, Consistently and Accurately
  - ✓ Review Reporting Criteria with Clinical and Engineering Experts
  - ✓ Ensure That a Complaint File is Opened
- Demonstrate Willingness to Take Necessary Corrective Actions to Improve Products and Their Labeling
  - ✓ Actions Meet the Test: "Is the Company Doing Everything Reasonable to Warn and to Protect?"
  - ✓ Corrective Actions are Taken Quickly and Audited for Effectiveness
- Address Servicing Issues Responsibly
  - ✓ Assure that service operations are reliable and accessible
  - ✓ Respond to trends effectively
    - o Analyze increase in repair frequency
    - o Identify troublesome components

Understand the Quality System Regulation!

The Regulation Establishing Current Good Manufacturing Practices

- Read 21 CFR 820.198 – line by line with a cross-functional team.
- Read the preamble!
- Verify that every requirement is supported by an established procedure.

The word "complaint" appears 82 times in the Quality System Preamble and Regulation

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Regulatory Requirements 820.3(b) – Complaint Definition

- *"Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution."*
- *[Compare ISO 13485:2003: §3.4: Customer Complaint: "written, electronic or oral communication that alleges deficiencies related to identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market."]*

Regulatory Requirements 21 CFR 820.198(a)

Basic Provisions of the regulation:

- Maintain complaint files
- Establish and maintain procedures
- Establish a formally designated unit

Complaint handling procedures shall ensure that:

- Process complaints in a uniform and timely manner;
- Document oral complaints upon receipt;
- Evaluate complaints for reports of deaths, serious injuries and malfunctions requiring notifications to regulatory agencies.

Regulatory Requirements 21 CFR 820.198 (b)

- (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.
- [Compare ISO 13485:2003, §8.5 – Improvement: "If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4)".]

Regulatory Requirements 21 CFR 820.198 (c)

- (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be **reviewed, evaluated**, and **investigated**, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

Regulatory Requirements 21 CFR 820.198 (d)

- (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by §820.198(e), records of investigation under this paragraph shall include a determination of:

  1) Whether the device failed to meet specifications;

  2) Whether the device was being used for treatment or diagnosis; and

  3) The relationship, if any, of the device to the reported incident or adverse event.

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Creating a World-Class Complaint Management Process

- Members of quality organizations support complaint management in several ways, including:
  - Establishing the original and updated risk assessments
  - Conducting failure investigations and root cause analyses
  - Performing corrective and preventive actions
  - Applying appropriate statistical tools for complaint trending
  - Redesigning products and processes to improve performance
  - Managing complaint-handling operations

Complaint Handling Upon Receipt

- ***Review*** to determine if report meets the definition of a complaint
- ***Document*** product identity: product code, lot/serial number
- ***Assign*** an “alleged failure mode” code for tracking
- ***Evaluate*** to determine if complaint is potentially reportable
- ***Evaluate*** to determine if an **investigation** is required
- ***Establish*** priority for **investigation** (adverse event, failure to meet specs, severe business risk = HIGH)
- ***Determine*** if there is already a corrective or preventive action related to the complaint (open?, closed?)

When *Complaint Investigation* is NOT Required

- Documented evidence of a previous investigation(s) for similar complaints with an established corrective or preventive action.
- Product was not manufactured or distributed by firm.
- Issue is related to billing, shipping, routine servicing, delivery or suggestions for product enhancement.
  - ✓ These inputs are forwarded to appropriate department for their consideration as an opportunity for improvement.
- Reported information does not meet the definition of a complaint.

Closing a Complaint *Without Opening a Corrective Action*

- High correlation with complaints that have an established corrective action:
  - ✓ Is the CAPA still open?
  - ✓ Was complaint device manufactured before or after CAPA implementation?
- If product was manufactured after implementation of CAPA, QE must evaluate why there was a recurrence of the failure mode.
- Confirm that the alleged failure mode is consistent with subject CAPA.

Survey Feedback: Why Are Some Complaints Not Investigated?

- 40% “Failure investigation is already open”
- 53% “Adequate investigation performed”
- 52% “Corrective action already initiated for same failure mode”
- 23% “Device was not properly used”
- 34% “Complaint doesn’t involve a possibility that the device did not meet specs”

Ways That Firms *Get Devices Back*!

- Be responsive: have a courier or salesperson pick up the product.
- Provide free shipping and product replacement or credit.
- Provide customized shipping containers to provide prompt, damage-proof return of components from service centers.
- Educate the customer on company's corrective and preventive actions – tell them "What's In It For Them".
- Continue to follow up with the customer until you get the product back.
- If all else fails, send someone from QA, QE or R&D to the complainant's site.

Complaint Investigation

Extent of the investigation is a function of risk potential

- Risk Analysis to determine severity/risk of product failure
- Age, intended life or expiration date of product
- Device History Record review (aka Production Batch Records)
- Service and repair history
- Review of recent upgrades or field corrections
- Review of recent design and process changes
- Review of previous corrective actions
- Review of timing of previous corrective actions
- Review of labeling including warnings, precautions, contraindications

Final Quality Assurance Review of the File

- Confirm that all required information is included:
  - ✓ Adverse Event (MDR/Vigilance) report and investigation, if applicable
  - ✓ Failure codes assigned for use in trending
  - ✓ Risk analysis reviewed to determine if failure mode is occurring with greater frequency or severity than anticipated
  - ✓ Review device history record (production batch record) findings
  - ✓ Confirm completion of failure investigation and summary
  - ✓ Response generated for internal and/or external customers, if requested
  - ✓ Rationale for complaints remaining open beyond closure goal will be revisited weekly until closed

Proactive Product and Safety Surveillance

- Consider Adopting FDA's MedWatch Approach to Postmarket Surveillance
  - ✓ Reach out to users – tell them the 5 W's on the importance of reporting complaints.
  - ✓ Make it EASY to report complaints and return products for evaluation.
- Don't Be Satisfied with Passive Customer Experience or Service-Only Reporting
- Develop Tactics for Eliciting the Information Needed for Continuous Improvement – Train complaint analysts, prepare scripts for device types.
- Ensure that the Corporate Culture Recognizes and Values the Need to Report Safety, Compliance and Quality Issues:
  - ✓ Customer complaints
  - ✓ Adverse events
  - ✓ Service trends and unanticipated occurrences ("near incidents")
- Provide Feedback to Internal and External Customers Regarding Action Taken on Their Issue

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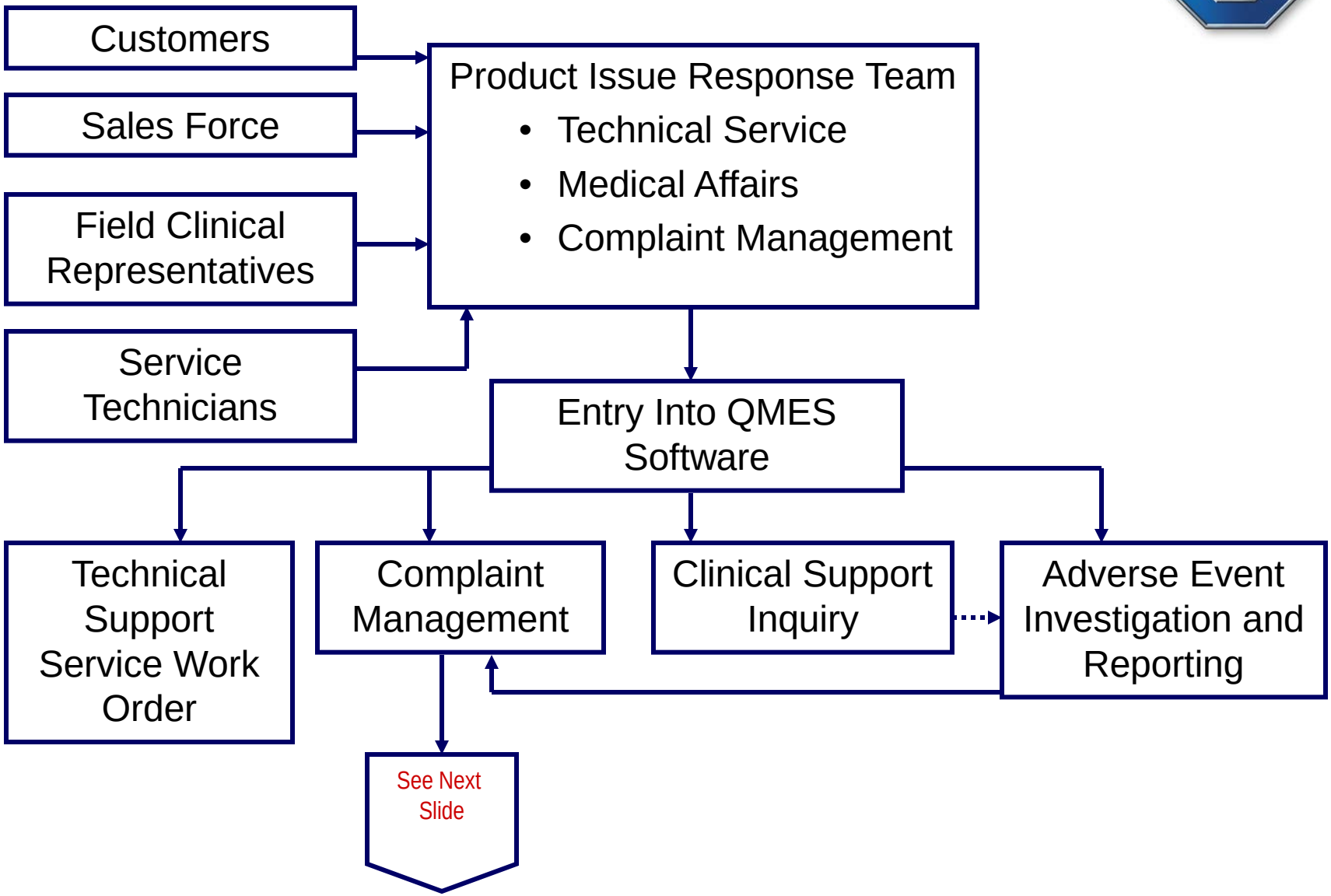
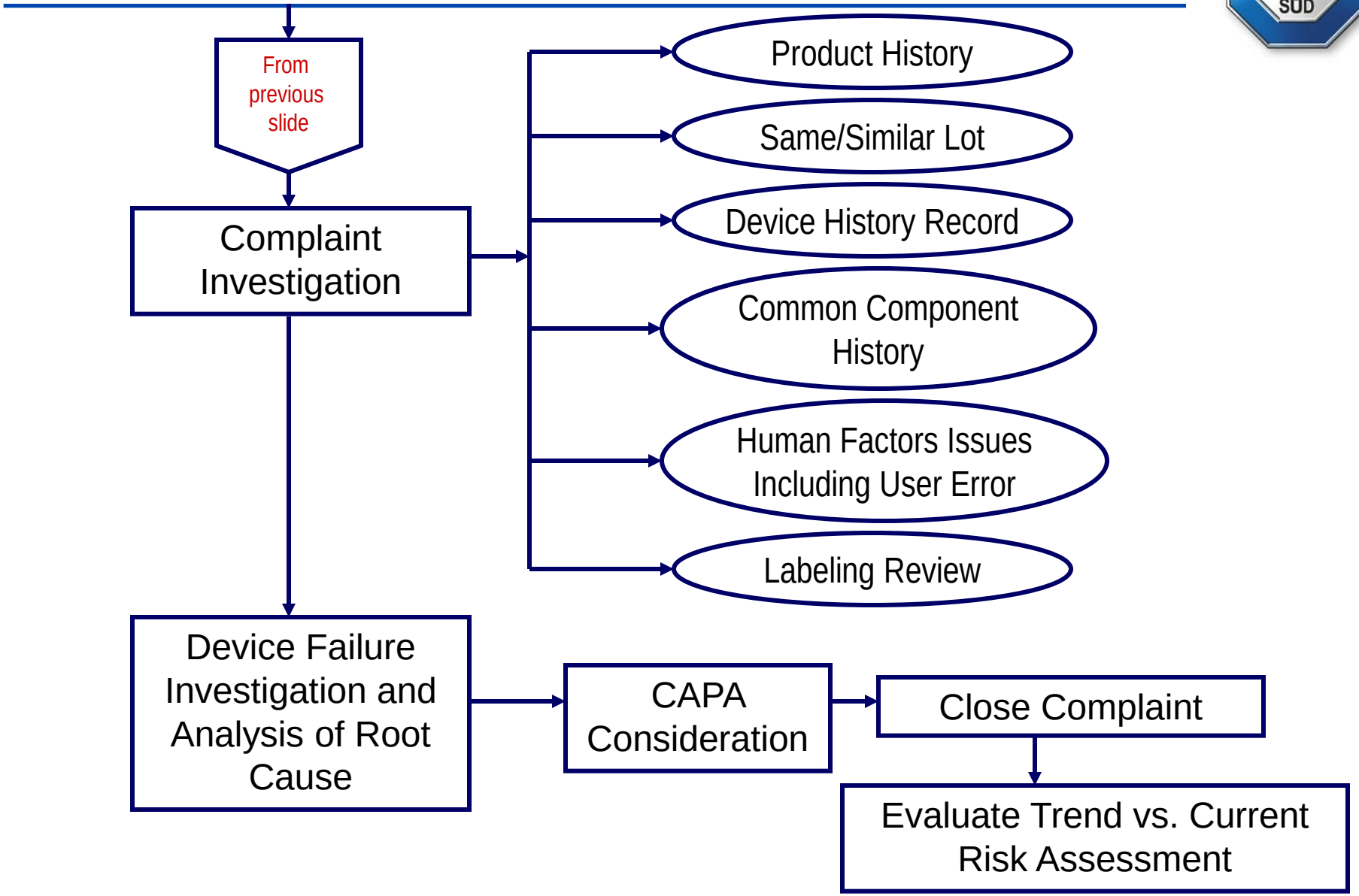
Field Experience Flow Chart - Product Issue Response Team (P.I.R.T.)



Field Experience Flow Chart - Product Issue Response Team (P.I.R.T.)



Product Issue Response Team (P.I.R.T.) – Structure & Process

- Designed to Assure That a Trained Professional Gathers Essential Safety, Performance and Customer Feedback Issues
- Co-location of Specialists:
  - ✓ Medical Personnel – Nurses with Product and Therapy Knowledge
  - ✓ Engineers – Provide Expert Problem-Solving Support
  - ✓ Complaint Analysts – Document and Investigate Complaints
- Team Lunch-And-Learns With Visiting Field Technicians and Local Experts:
  - ✓ Meet in the bullpen; huddle around the equipment; review sources of malfunctions and other complaints.
  - ✓ Quality Engineers request input on problem areas and root cause.

Product Issue Response Team (P.I.R.T.) – Structure & Process

- Use Scripts to Ensure that Needed Information is Captured During the Call in a Consistent Manner Among P.I.R.T. Personnel and from Caller to Caller.
- Don’t miss an opportunity to obtain critical, valid and thorough information from complainants!
  - ✓ Facts needed for reports of death and serious injury.
  - ✓ Fulfill requests for medical or technical consultation.
  - ✓ Gather needed information on product performance complaints to help identify root cause.
  - ✓ Provide timely technical support if required by phone or in the field.

Product Issue Response Team (P.I.R.T.) – Advantages

Co-location Facilitates Communication

- Access to products for hands-on training for reported failure modes.
- Bullpen discussions of emerging failure modes.
- Incoming Calls Pertaining to Injuries, Complaints and Requests for User Support Go Directly to Co-located P.I.R.T.
- Warm handoff or specified number in company's recorded greeting.

Reduced Dependence on Customer Service Personnel (Order-Takers)

- Less opportunity for errors or omissions.
- Removes conflict with time-based goals for other tasks.
- Simplifies training challenges related to skills and turnover.

Product Issue Response Team (P.I.R.T.) – Advantages

A Proactive Approach like P.I.R.T. Allows a Company to Harvest those Rare “Pearls of Wisdom” that Could Be Lost Later.

- Complainant is a difficult-to-reach, night-shift nurse.
- Delay results in complainant’s inability to remember details of the complaint or adverse event.
- Risk management at facility prohibits communication.
- Complaint device has been misplaced, corrupted or discarded.

Lessons Learned – KAIZEN EVENTS On Complaint Management

- Indications that the Kaizen Approach Was Needed:
  - Lack of a consistent reliable process among divisions.
  - Large number of open complaints awaiting evaluation; backlog was continually increasing.
  - Excessive cycle times for complaint processing.
  - Risk that open complaints could contain critical safety and performance information.
  - Delays in receiving complaint units back for timely evaluation.
  - Recurring regulatory inspection/audit citations for complaint management deficiencies.

Lessons Learned – KAIZEN EVENTS On Complaint Management

- Indications that the Kaizen Approach Was Needed – Continued:
  - Exposure to risks from lack of timely complaint processing:
    - Compliance – FDA and other regulators' inspection/audit findings.
    - Liability – Perception of lack of sufficient diligence toward safety and performance.
    - Business:
      - » Delay in implementing corrective actions to prevent recalls.
      - » Erosion of customer confidence in the product or service.
      - » Risk of market share erosion.
      - » Cost of Poor Quality.
    - Company Culture – Employee satisfaction, retention, turnover.
      - » Impact of recurrences of complaints and field actions on morale.

KAIZEN EVENTS On Complaint Management – Improvements

Sample of Table Capturing Inputs and Analysis of Areas of Waste and Improvement Ideas:

Categories	What's Not Working	Business Unit	Ideas and Countermeasures	Impact	Effort

- Improving the Quality, Timeliness and Simplicity of Complaint Intake:
  - Inconsistent routing and criteria for complaints from customer service
    - Create dedicated customer service team to screen complaints prior to forwarding to the complaint department.
  - Forms too complicated; redundant information; multiple contacts.
    - Team revised forms to include necessary data; only one used per customer.
  - Multiple formats for management reports on complaint status.
    - Establish one format for periodic complaint reports for monthly meetings.

KAIZEN EVENTS On Complaint Management – Improvements

- Obtaining Product Samples Back Quickly for Failure Investigations
  - Individual products sent to multiple locations for analysis.
    - Lack of standard procedure for returns regardless of who was returning the sample or what site manufactured that particular product.
  - Different sites had different timelines and procedures for investigations.
    - Establish a standard, required turnaround time for conducting analyses.
    - Develop general procedures for product investigations to reduce variability.
    - Conduct training for engineers who performed failure investigations.
  - Some processes were not required for failure analysis.
    - Eliminate product decontamination for returned products with no health risk.
  - Product failure codes not used consistently thus compromising analysis.
    - Redefine codes for reported failure mode and confirmed failure mode.

KAIZEN EVENTS On Complaint Management – Improvements

- Establishing Options for Closing Complaints When Contact With the Complainant Could Not Be Accomplished.
  - In some cases, team was unable to contact complainant after ≥ 3 tries.
    - Established valid reasons why complaints could be closed absent contact with the complainant.
    - Established process for maximizing ability to learn from the report as received using other data (reports on similar products, other users, etc.)
  - Lack of defined methods to be used for follow-up when no response received on a serious complaint.
    - Process was defined to cover escalation in instances of serious complaints involving harm: telephone, site visit by company personnel.
    - Contacting others at the site: risk managers, site administrators, etc.

KAIZEN EVENTS On Complaint Management – Improvements

- Simplification of Complaint Closure
  - Complaints are not evaluated in a timely manner upon receipt.
    - Establish groundrules for closure including some or all of the following:
      - Report does not meet the definition of a complaint; forward elsewhere
      - Product manufactured by another company; forward as appropriate.
      - Corrective action already open for this failure mode.
      - There is no possibility of obtaining a returned products for analysis.
- Expediting Reports From International Locations
  - Inconsistent understanding of forms and procedures among regions.
    - Global team to develop one form applicable to all regions.
  - Lack of a standard requirement for timeliness of completion of follow-up investigations with international complainants.
    - Review of individual country requirements as basis for standard timeframes.
  - Lack of feedback to regions on actions taken to correct product failures.
    - Awareness that feedback increases commitment and cooperation.

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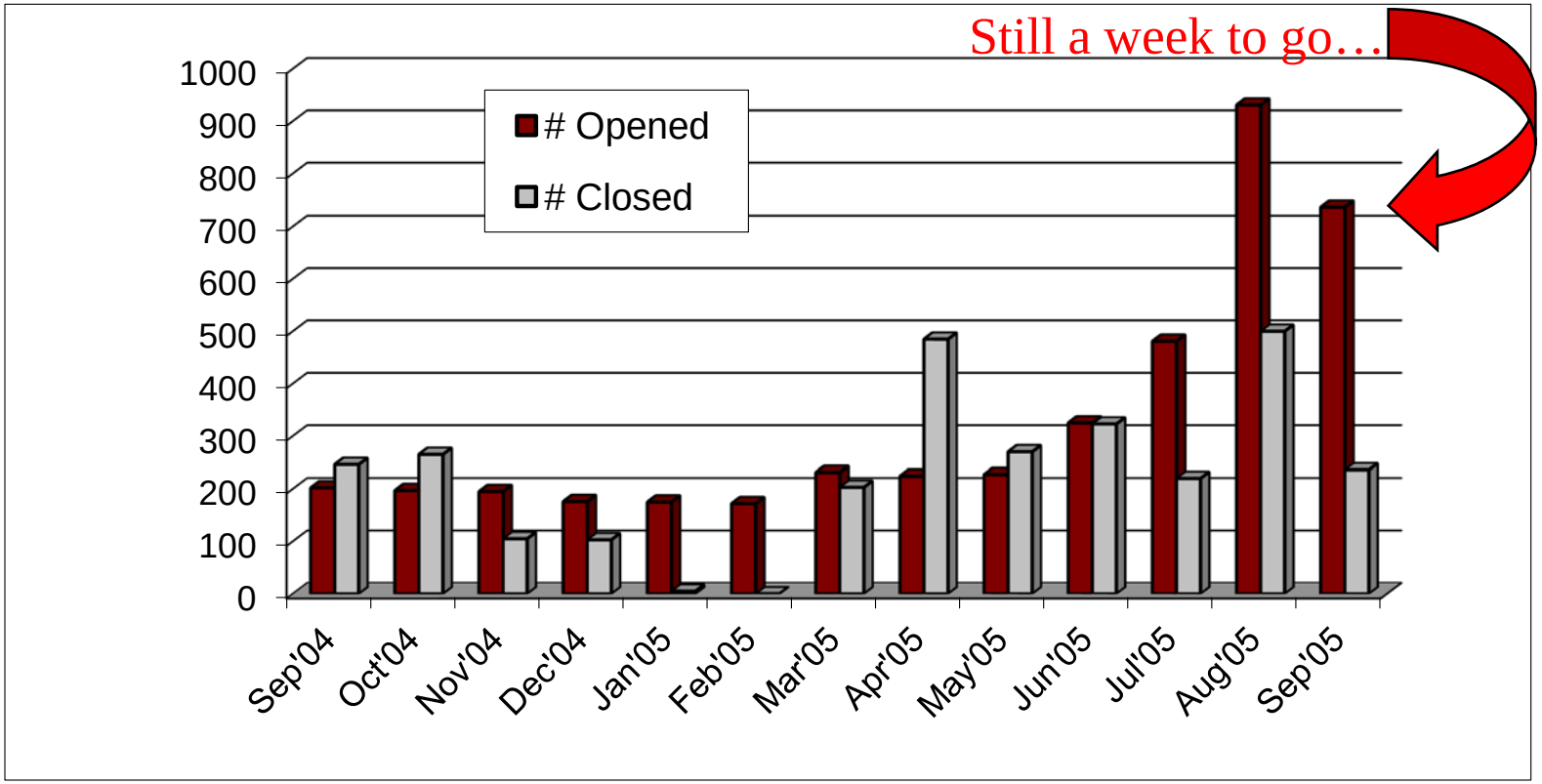
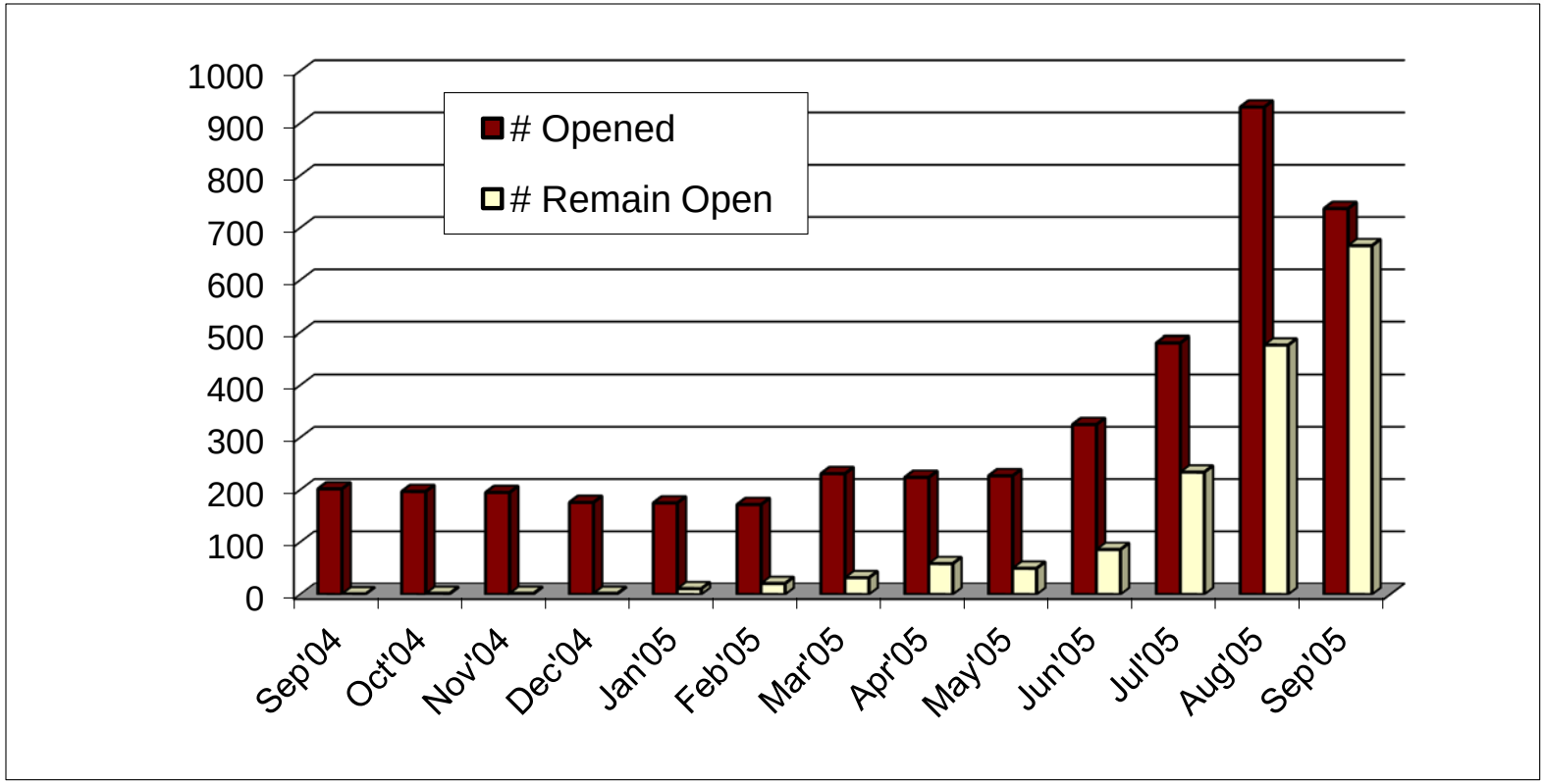
Complaints Open/Closed *(Sample Presentation of Metrics)*



Dec ’04 – Feb ’05: Complaint process redesign period – few complaints closed.

May ’05 – Aug ’05: Campaign to increase complaint and service experience reporting from all sales, service and customer support personnel.

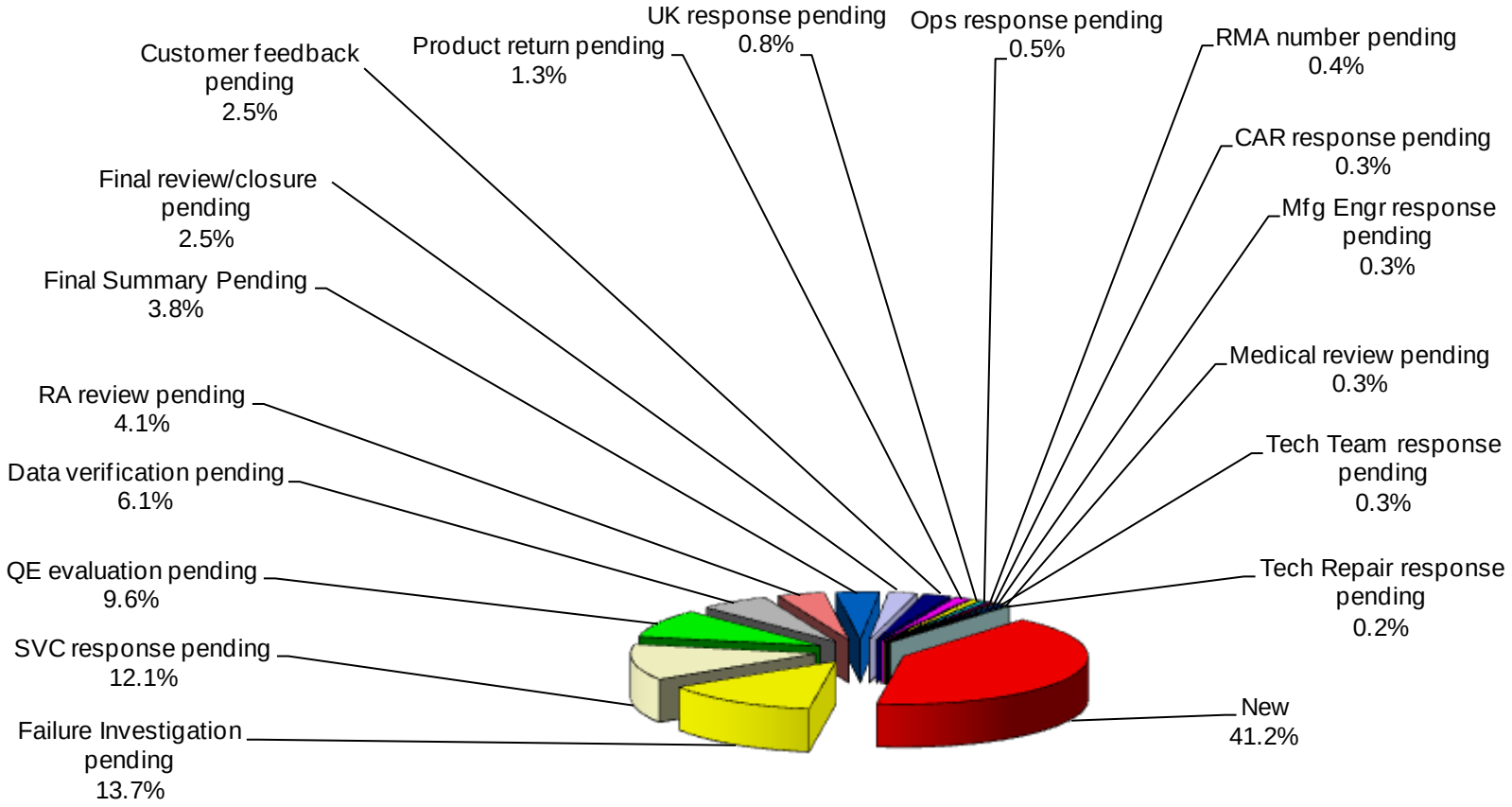
Complaints Open/Closed *(Sample Presentation of Metrics)*



Increase in complaint input preceded increases in staff support requiring extra effort to close complaints in a timely manner.

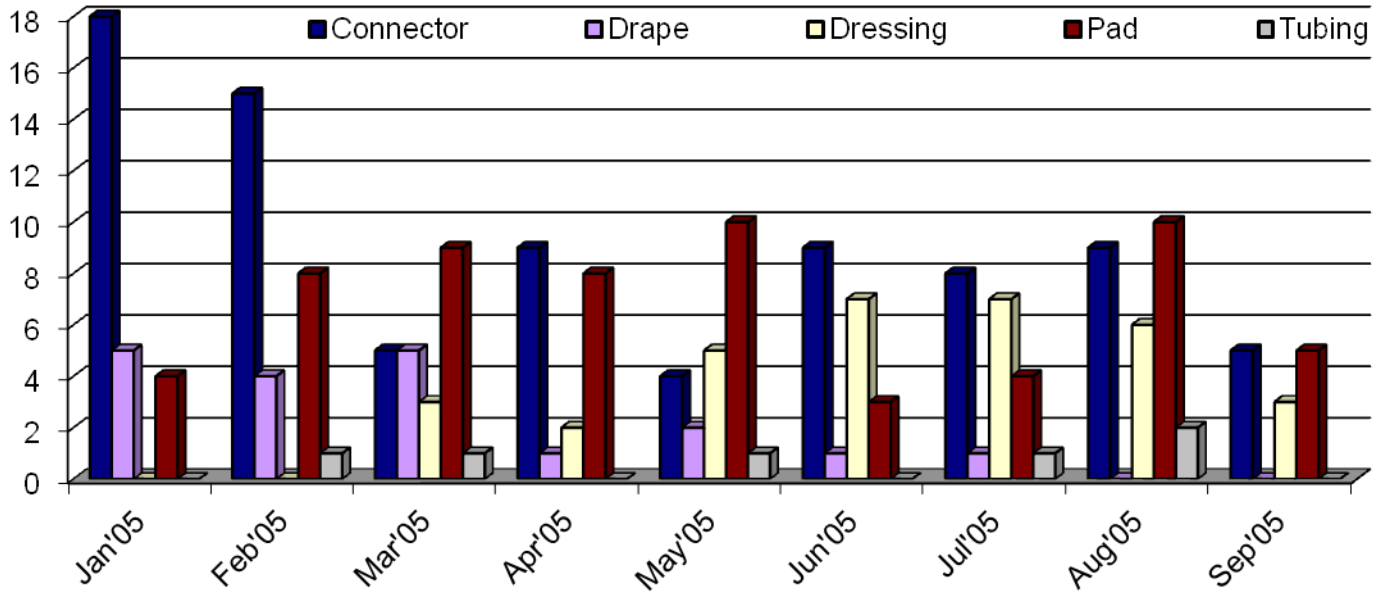
Advantage: more detail regarding known failure modes; additional returned samples for analysis.

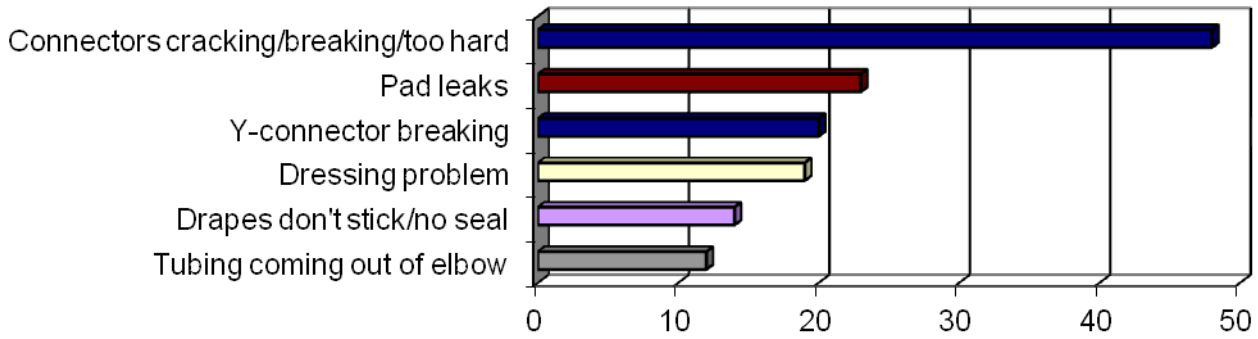
Status of Open Complaints *(Sample Presentation of Metrics)*



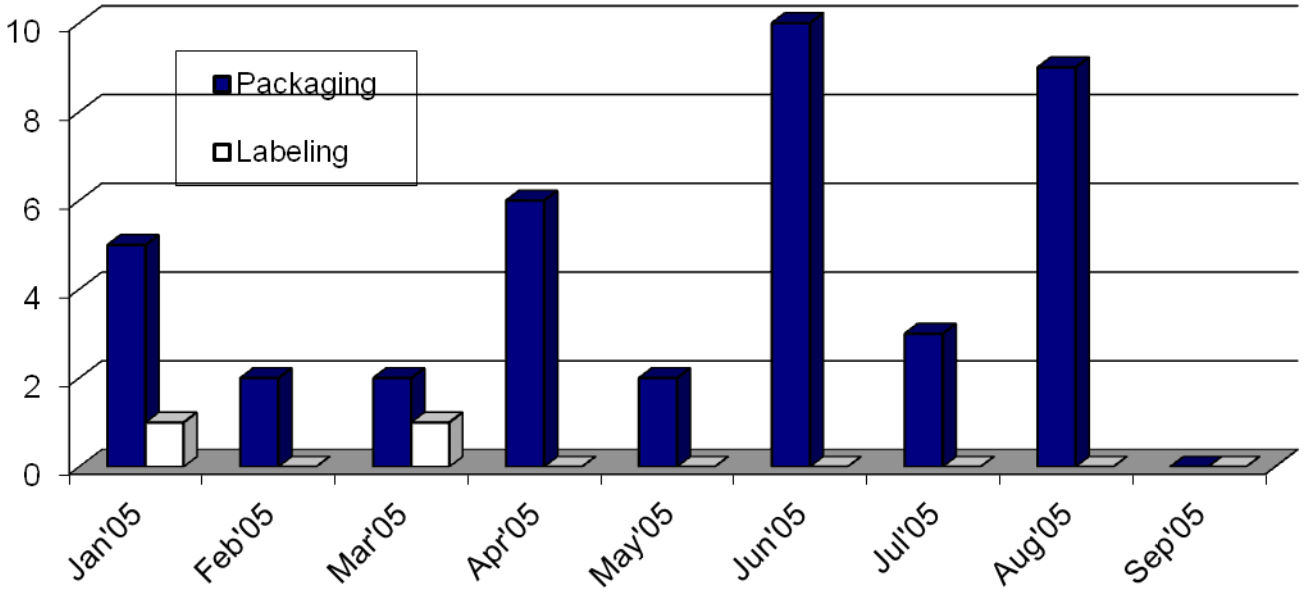
Complaint department's tool for identifying root cause of open complaints.

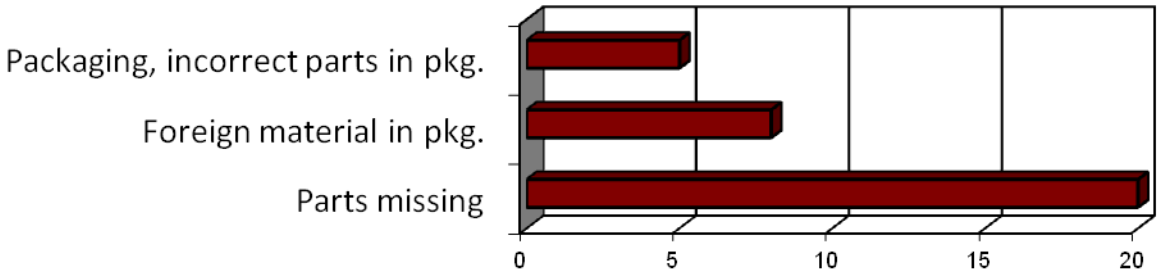
Disposables – Dressings *(Sample Presentation of Metrics)*





Disposables – Packaging *(Sample Presentation of Metrics)*





Contact us today

Thank you for attending!

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