

# QP Forum Good Deviation Trends

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# PCI Pharma Services

- ✓ CDMO
- ✓ Global Footprint
- ✓ Team +600 (Ireland)
- ✓ 4 Locations (East Coast)
- ✓ 8 Facilities
  - Commercial Packaging
  - Clinical S&D
  - Analytical Laboratory
- ✓ 2 Commercial MIA
- ✓ 1 Clinical IMP
- ✓ QP Certification
  - Commercial Supply Chains
  - Clinical Supply Chains



# Good Deviation Trending

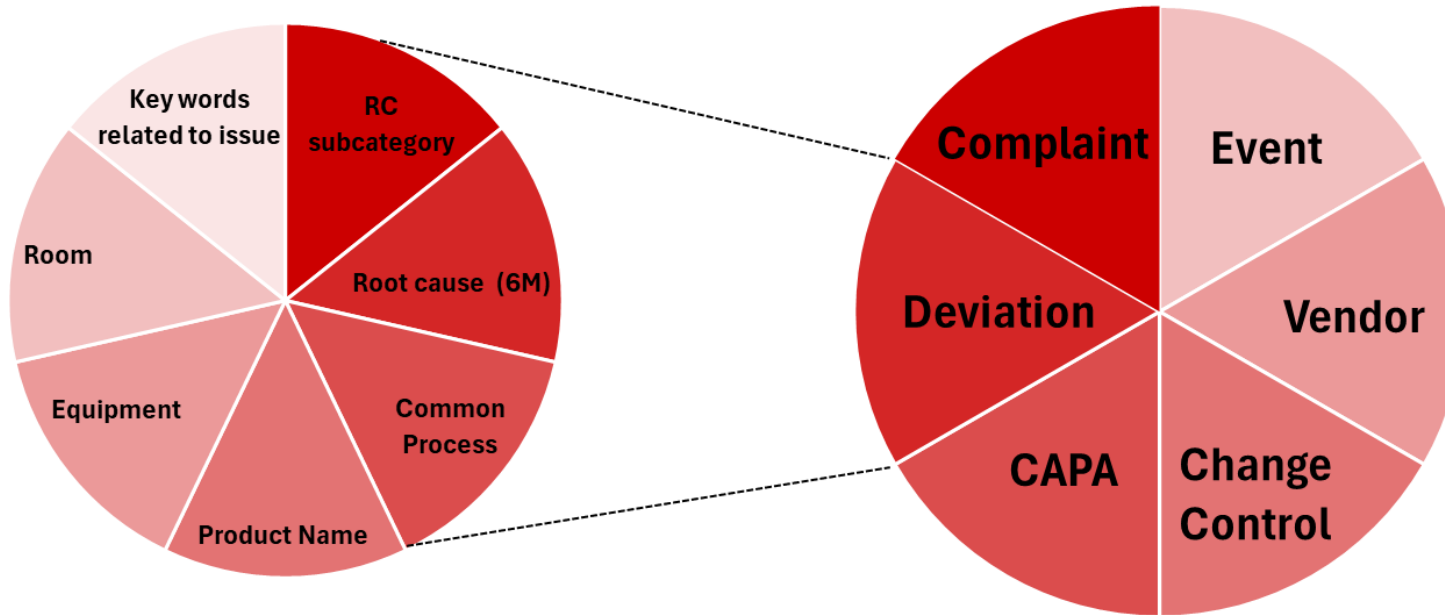
- ✓ Trend: A pattern detected from the examination of records or the output of statistically appropriate methodology.
- ✓ Recurrence: The repeat occurrence of the same event in a similar context due to the related root cause .



Frequency of Activity	Minimum Timeframe to Search
At least Daily	6 months
At least Weekly	12 months
At least Monthly	24 months
>Monthly or unsure	24 months



# Good Deviation Trending



## Record Level (Deviation):

- Root cause category (6M)
- Root cause subcategory
- Common process
- Product Name
- Equipment
- Room
- Key word search

## Trending/Linkage:

- Events
- Deviations
- Complaints
- CAPA
- Vendor Non-conformance
- Change Control

## QMS Review Mechanisms

- Record Level (Deviation)
- Monthly QS Review
- Biannual QMR (Site)
- Customer QMR
- Regulatory Inspections
- PQR

# What does Good Trending Look Like?

- ✓ Must be relatively straight forward to trend, system design
- ✓ The QMS identifies True trends
- ✓ Data is understandable for internal and external stakeholders
- ✓ QP is aware in real time of emerging trends
- ✓ Appropriate CAPA identified
- ✓ CAPA effectiveness assessment to identify repeat trends

# PCI Learnings

- ✓ Master Control does not have built in data analytics
- ✓ Trending is a Manual process
- ✓ Raise a Trending CAPA
- ✓ Trending at record Level is part of the picture, linking across QMS is key
- ✓ Review of trends “in cold light of day” independent review can help detect trends
- ✓ Cross departmental review helps understand what the data is telling us
- ✓ As technology advances with Master Control the ability to pick up and link trends will become more automated.

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Thank you**

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# What does Good Deviation Trending look like?

Presenter : Karen McCarthy, Site Quality Head

**Johnson & Johnson**  
Innovative Medicine





# What we do at Johnson & Johnson Biotherapeutics Facility Cork



## Main Markets Served



EMEA



APAC



NORTH  
AMERICA



LATIN  
AMERICA

## Technologies

- Biotechnology API Production
- Perfusion
- Fed Batch
- Purification
- Disposable Process Capabilities
- Commercial & Clinical



Capacity of  
Bioreactors

1,000L  
2,000L  
15,000L

# What does Good Deviation Trending look like?



Standardization of Data using Drop down Field



What does the QP Want to See in a Deviation



Integrated Real-time Data Analytics



Structured reporting for HA requests



Utilizing a multilingual analytics engine to analyze nonconformance recurrences



Risk Assessment Capability built in

# Thank You