

HOW-TO WORKFLOW

Implementation of our Monocyte Activation Test (MAT), the PvroMAT® system

TRAINING

(recommended)

FEASIBILITY

Check that MAT is suitable for the sample (no interference)

In case of interference, method development with specific sample preparation can be tried to tackle the issue

COMPENDIAL?

Is MAT compendial in the reference regulatory quideline?

(EU, India, Russia)

(US, Japan, China)

ND

PRODUCT SPECIFIC VALIDATION (PSV)

PSV is performed on 3 lots of sample to check:

- Acceptance criteria for validity of the endotoxin standard curve
- Test for interfering factors
- Detection of non-endotoxin contaminants
- Interference in the detection system

FILE SUBMISSION

To Regulatory Bodies

ROUTINE TEST

VALIDATION Robustness, Accuracy, Precision,

FULL METHOD

Specificity, Quantitation Limit, Linearity and Range of applicability.

PRODUCT SPECIFIC VALIDATION (PSV)

PSV is performed on 3 lots of sample to check: Acceptance criteria for validity

- of the endotoxin standard curve Test for interfering factors Detection of non-endotoxin
- contaminants Interference in the detection
- system



RAININGS OFFER

SERVICES Feasibility study

APPLICATION

- Method development
- Method development consultancy at your site or remotely
- Implementation troubleshooting Software data analysis for routine
- testing

SERVICES Product specific validation consulting

VALIDATION

- at your site or remotely Data analysis for product specific
- validation (PSV)

TRAINING SERVICES REMOTE

SCHOOL

Pyrogen Testing

- Learn about

the MAT

E-LEARNING How to use the PyroMAT® system • Interactive experience—a

- fun way to learn • Screens, videos, anima-
- tions, games • Learn at your own pace
- Duration 20-30 minutes • Certificate after passing a

quiz

- Regulatory context and operating principle
- Implementation, validation, methods Test procedure demo,
- result analysis • Good practices, tips and
- tricks, data integrity Open consultancy part
- Personalized and interactive experience Duration: up to 5h

Method

REMOTE

Development Consulting for PyroMAT® system

Parameters to assess to

- demonstrate the compatibility of your product Guidance on adjustment of the method in case of
- interference coming from the product Recommendation on the
- most appropriate method to use routinely Demo of the PyroMAT® system
- Training on data analysis Duration: up to 5h + follow-up of the tests

HOW DOES IT WORK? PyroMAT® system: the only cell-line based pyrogen test

Pyrogens

gram-negative bacteria Non-Endotoxin

Endotoxins

Pyrogens (NEPs) gram-positive bacteria,

Mimics the human immune reaction

yeast & mold, virus...



Detection of IL-6 with

IL-1β, IL-6, TNF-a, IFN-y

Cytokines

ELISA test

No more animal-based pyrogen tests Shift from animal-based testing to in vitro testing.

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NOW IS THE TIME!

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PyroMAT® System

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