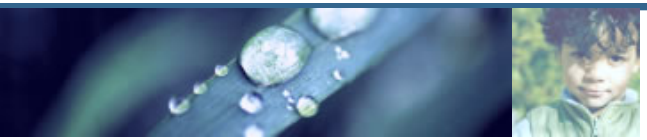

Value of Test Data to Validate Effectiveness of Seafood Safety Control Programs

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Conference for Food Protection

Orlando, FL

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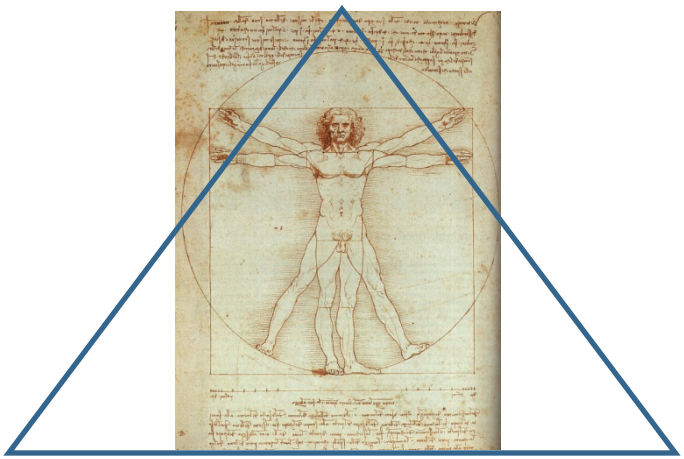
Eurofins' Mission is Health and Safety

Food
#1 worldwide



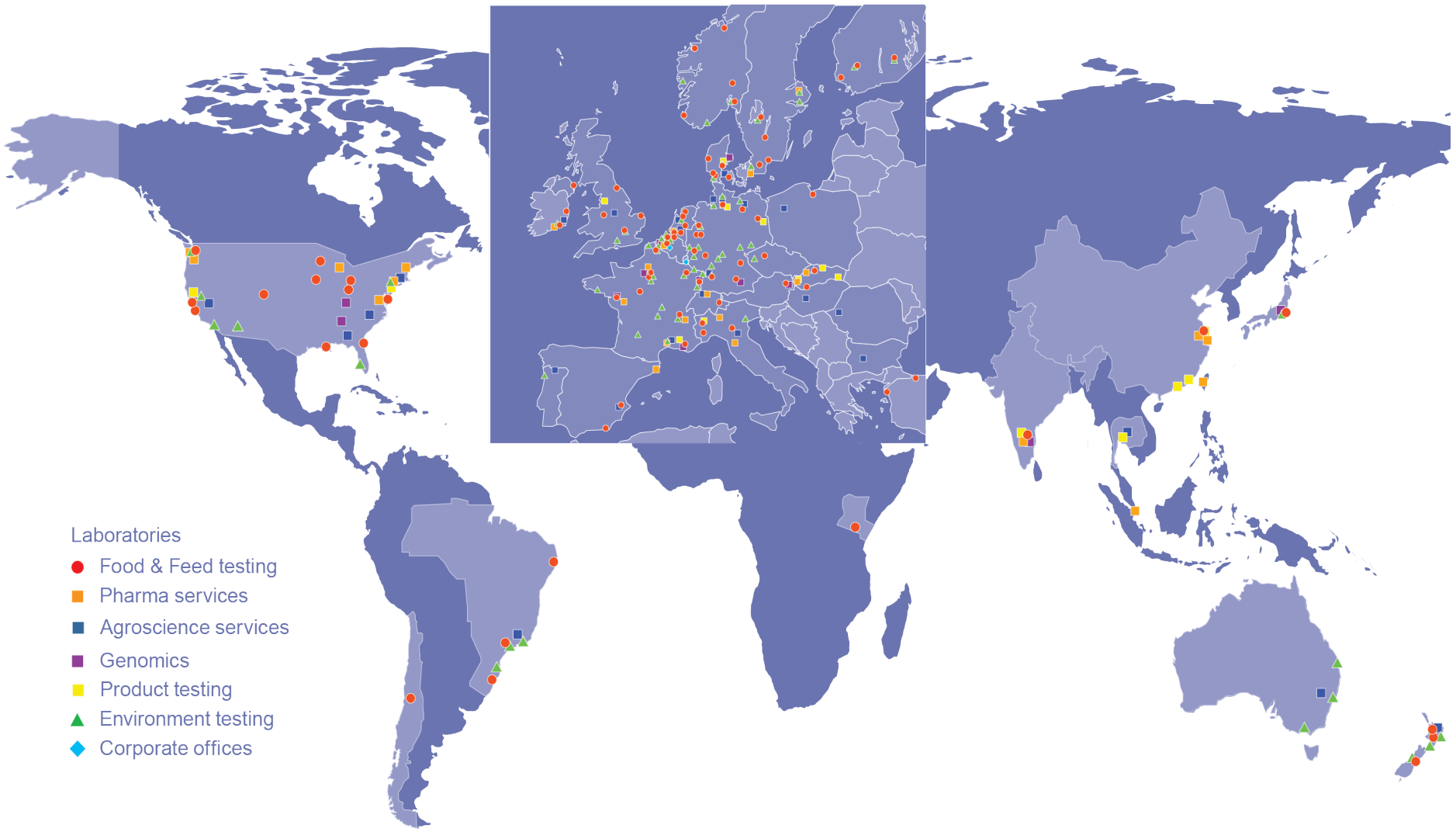
Environment
#1 worldwide

Pharmaceuticals
#1 worldwide

Our Mission:

To contribute to global health and safety by providing our customers with high-quality laboratory and advisory services while creating opportunities for our employees and generating sustainable shareholder value

Eurofins International Network of World-Class Laboratories



Old School Pillars of Food Safety

- Good Manufacturing Practices (GMPs)
- Sanitation Standard Operating Procedures (SSOPs)
- Hazard Analysis Critical Control Point Program (HACCP)

New School Pillars of Food Safety

- Environmental Monitoring Program (EMP) – pathogens & allergens
- Supplier Verification Programs – don't inherit your suppliers problems
- Audits – naivety in use

Additional Preventive Control Programs

- Training programs for managers and/or workers
- Written records, e.g., batch records, sanitation records
- Validation of control measures
- Written sanitation SOPs
- Food label review and control program
- Testing of in-coming raw materials, in-process materials, finished products, and processing environment

Nobody's nose knows

FSMA New Testing Requirements

- All affected food must be evaluated for safety – final product and environmental testing

- Monitoring requirements must verify that controls are working correctly

FDA Guidance on Pathogen Testing

- Use proper sampling techniques
- Ensure adequate sample handling
- Use an approved testing method
- Lethality steps must be validated
- Maintain control of products until test results are complete
- If a sample tests positive, the entire lot/batch is considered positive
- Subsequent negatives from the same lot do not negate a positive result

Risk Analysis – The First Step in Control

- Manufacturers not currently operating under HACCP should strongly consider implementation to manage food safety risks
- With or without HACCP, a pathogen and residue risk analysis should be conducted and documented to outline issues of concern
- Risk analysis should include
  - Raw materials/suppliers review
    - Facility Audits, Specifications, Certificates of Analysis, Verification Testing
  - Finished product profile to determine if it supports growth of pathogens
    - pH, water activity, final packaging, etc.
  - Direct Human Contact (DHC) considerations
  - Lethality steps
  - Post lethality environment controls

Raw Materials Control

- Verify your supplier's controls – don't inherit supplier problems
- Verify transport method/equipment is not a contamination source
- Sanitize thoroughly to ensure equipment/facility is not contaminated – test to ensure facility is pathogen free
- Include pathogen screens for every lot where you have no kill step
- Continue routine test screening of your finished products
- Pathogen control program should include steps for product disposition if it is found to be contaminated

Raw Materials Testing Considerations

- Raw materials should undergo the full regimen of analysis typically required by the receiving company to verify COA's

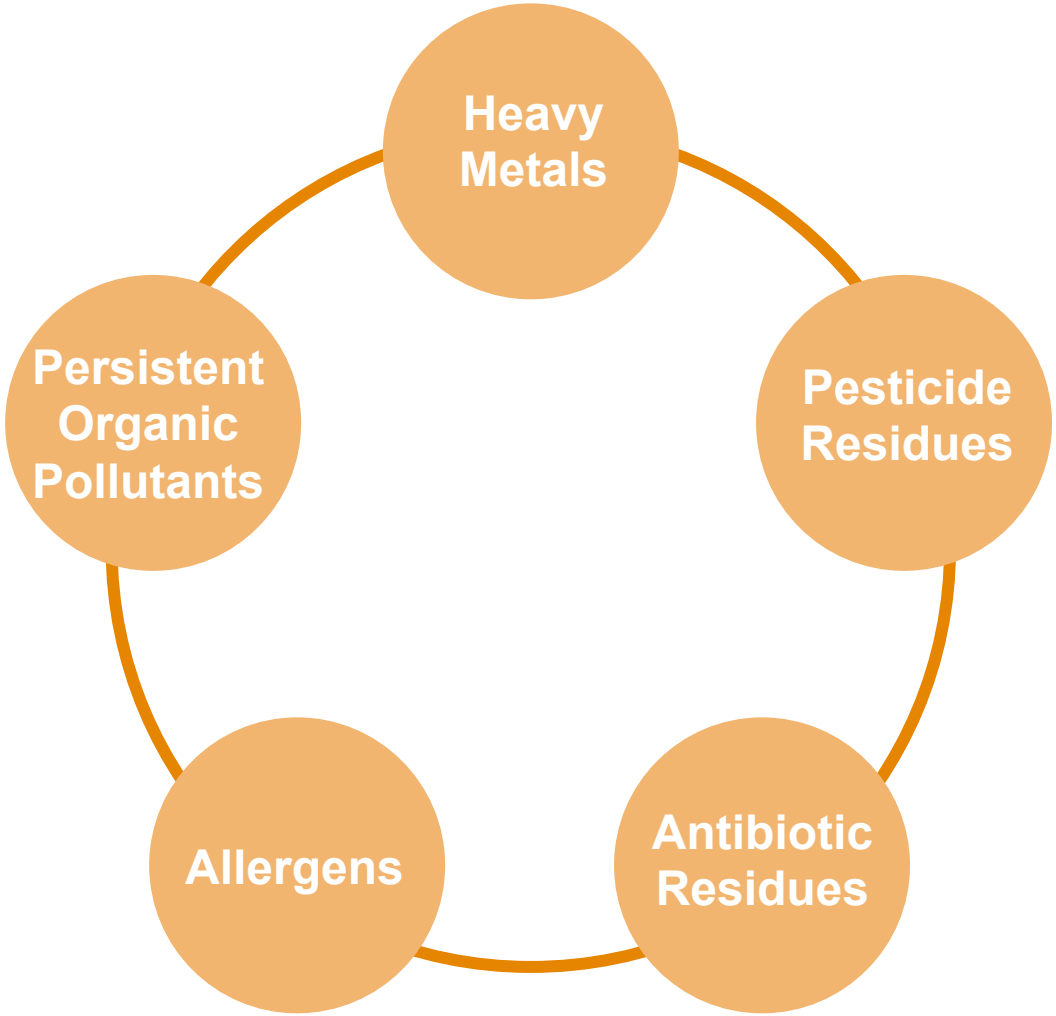
  - If specifications and/or COA's do not exist, implement

- Analysis set should include pathogens, allergens, or residues if risk analysis determines they are a hazard likely to occur
- Manufacturer should consult with their laboratory on test methods best suited to their raw materials/products/program goals
- Know what you plan to do if a pathogen/allergen/residue is found… before you do any testing
- An effective audit of the supplier's facility and its programs can identify high-risk suppliers
- If product is direct harvested, more reliance on testing may be needed

Why Test for Pathogens?

- Brand protection and liability reduction
- Regulatory expectation
- Validate effectiveness of CCP interventions such as heating, cooling, irradiation, sanitation, etc.
- Validate effectiveness of environmental control program
- Validate purchase specifications by you or your customers
- Outbreak investigations

Chemical Contaminants



Why Test for Harmful Chemicals?

- Brand protection and liability reduction
- Regulatory expectation
- Validate effectiveness supplier verification programs
- Validate effectiveness of environmental control program for allergens
- Validate purchase specifications by you or your customers
- Outbreak investigations

Cost of Not Testing

- Potential for injuring or killing your customer
- Intrinsic and extrinsic costs associated with recalls
- Damaged brand reputation
- No liability protection – does liability increase due to lack of prudence?

Its Real!

China

- 51% failure rate due to “major” defects in food processing plants – Asia Inspection, 2011

Europe

- 1,200 tonnes of fake or poor quality products seized in 2 month period (Dec 2013 - Jan 2014) – Europol, 2014

Salmonella in Seafoods

- Heinitz et al., J. Food Prot., 2000 FDA Data
- Analyzed 11,312 import and 768 domestic seafood samples over a 9-year period (1990 to 1998)
- *Salmonella* incidence
  - imports 7.2%
  - domestic 1.3%
- Incidence rate in 2,734 RTE import seafood samples was 2.6% - included cooked shrimp, shellfish or fish paste, smoked fish, salted/dried fish, and caviar

- Ponce et al., Food Micro., 2008 seafood prevalence paper
- Amagliani et al., Food Res. Int., 2011 review paper

FDA Sushi Investigation

- Moon Fishery (India) Pvt. Ltd, Kerala, 4/19/12 – 4/24/12
- Numerous HACCP Plan Issues
  - No CCP for pathogen control in processing plant during cutting, scraping, and vacuum packaging
- Numerous GMP Issues
  - Insufficient monitoring of sanitary conditions and practices
  - Insufficient monitoring of water used on food and food contact surfaces, hand washing, toilets, and for manufacturing of ice
  - Bird feces, insects, and filth found in ice manufacturing equipment
  - Product residue found on utensils and on ceiling after cleaning

FDA Lab Results

- Yellowfin tuna samples analyzed by FDA – 28 nakaochi scrape, 2 saku (whole muscle sashimi), 1 strip
- 3 nakaochi scrape and 2 saku samples were negative
- 24 nakaochi scrape samples were positive (86% incidence)
  - 10 *Salmonella* Bareilly
  - 3 *Salmonella* Nchanga
  - 11 both *Salmonella* Bareilly and *Salmonella* Nchanga
- 1 nakaochi scape and 1 strip in progress
- All positives indistinguishable from outbreak strains by PFGE

- Shabarinath et al., Int. J. Food Microbiol., 2007 - found a 52% *Salmonella* incidence in SW Indian seafood products. Kerala is in SW India!

What Is A Third Party Laboratory

“If the laboratory wishes to be recognizsed as a third party laboratory, it should be able to demonstrate that it is impartial and that its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment”

“Organisations external to the laboratory cannot influence the results of tests carried out”

From EN ISO/IEC 17025

What Is A Third Party Laboratory

To be a true third party laboratory, there are two essentials:

Independence

Impartiality

Independence + Impartiality = Credibility

The Good

- Lab Accreditation – insource or outsource lab performance and quality expectations
- More emphasis on controlling hazards at receiving step ➔ supplier verification testing
- More emphasis on validating control programs
- More emphasis on environmental monitoring testing
- New detection platforms and methods
- Strain source tracking
- Electronic data access and management tools

The Bad

- Reduced emphasis on end product testing
- Lack of retailer interest in testing ➔ weak link!
- Lack of importer, processor & distributor understanding of test methods and ability to interpret results
- Over reliance on auditing for purchase decisions
- Lack of well-trained technicians in the industry
- Academic community developing good bench-top molecular biologists with little practical understanding of food processing

The Ugly

- Too many laboratories performing tests they know little about
- Too many short cuts being used in laboratories to save money and increase profits
- Too many companies creating false COAs
- Too much conflict of interest with internal laboratories and some government-sponsored laboratories

Building a Robust Analytical Services Infrastructure

- Technical expertise
- Technology platforms
- Quality control programs
- Information technology
- Logistics
- Customer service

Technical Expertise

- Do your laboratory managers possess academic degrees appropriate to management responsibility?
  - Chemists running chemistry departments
  - Microbiologists running micro departments
- Do your bench-top technicians have academic training appropriate for job tasks?
  - Math skills to do dilution problems, analyte quantifications, results interpretation
  - Test platform operational knowledge
- Do you have regular training programs for all laboratory staff?

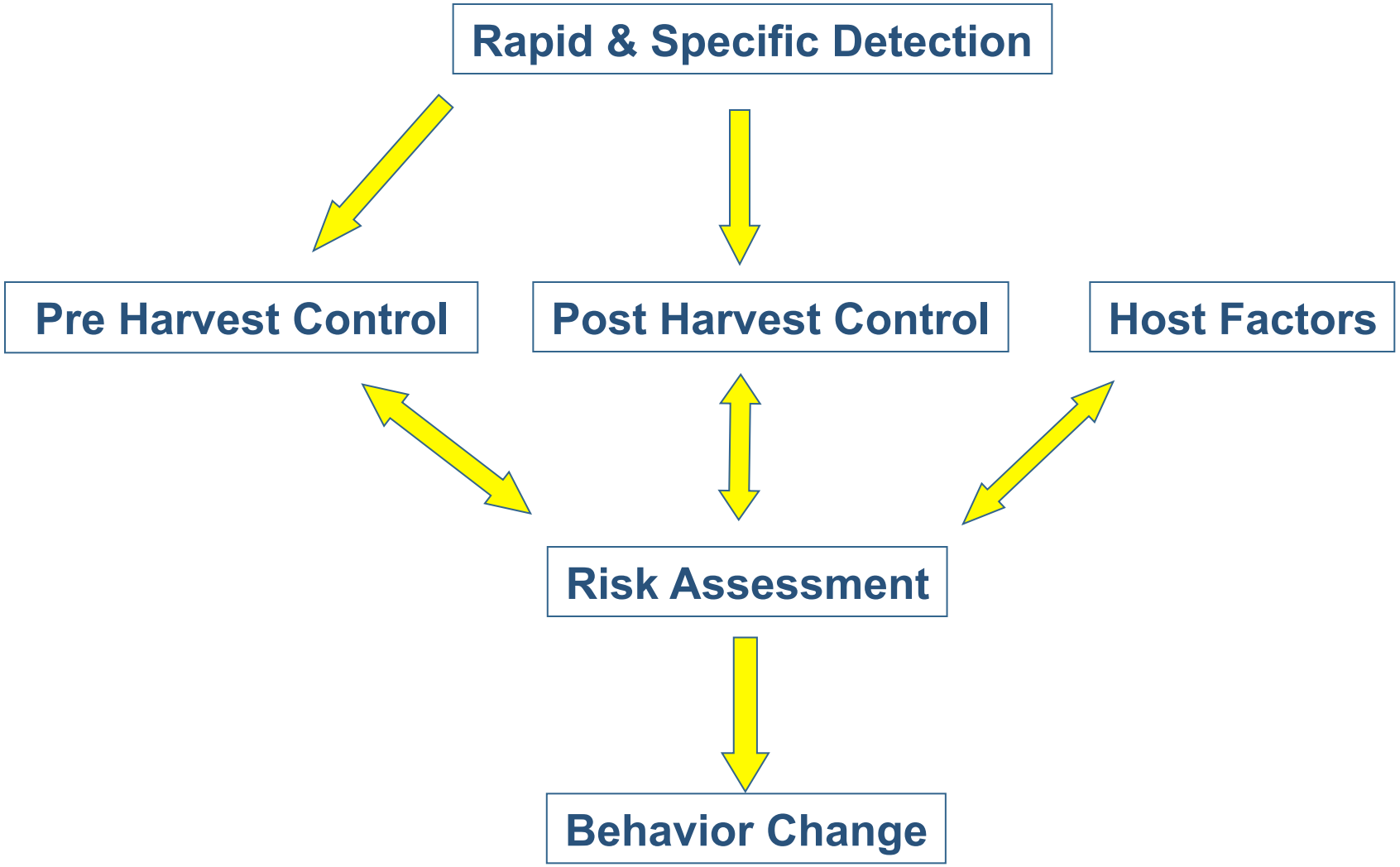
Technology Platforms (kits & instruments)

- Is the platform validated for matrix and analyte?
- Are you really measuring the analyte of interest?
- Is there instrument drift?
- What is the precision and accuracy of the method?
- What is the calibration frequency?
- Does the platform have regulatory approval?
- Does the platform have broad industry acceptance?
- Are you using fit-for-purpose platforms?
- Is the platform robust for frequent use?
- Are reagents of high quality and readily available?

Quality Control Programs

- Does your quality management system follow ISO 17025 standards?
- Is the laboratory independently accredited?
- Do you have a robust laboratory information management system for safe data archiving?
- Are proficiency tests used to ensure accurate results?
- Are you running positive and negative controls?
- Do standard curves have more than two data points?
- Does cost, speed, and ease of use trump precision and accuracy?

Food Safety Paradigm





Thank you for the opportunity to provide this overview

We look forward to working with you in the future