FROM DAYS TO HOURS: THE CLOSEST YOU CAN GET TO REAL-TIME STERILITY TESTING FOR CELL & GENE THERAPIES

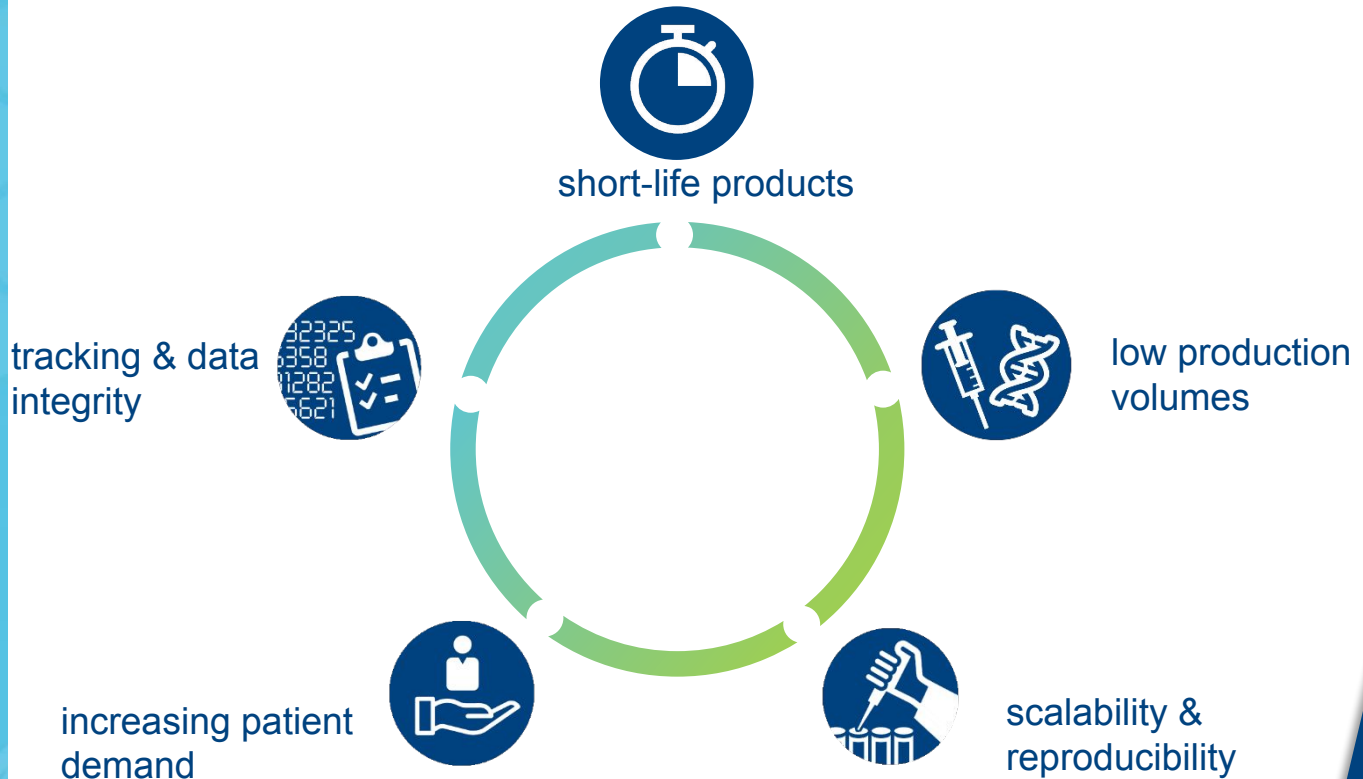
2026 | Auktumas JURGUTIS, Solution Manager

CELL-BURST is the first **same-shift** sterility test for C&GT products, with proven **equivalency** to compendial methods

AGENDA

- Challenges in the Cell & Gene Therapies (C&GT) manufacturing
- Focus on sterility time to result
- Solution discovery & quick overview
- Validation approach & Results
- Conclusion

C&GT MANUFACTURING CHALLENGES AND NEEDS



CELL & GENE THERAPIES

Removing sterility testing as a bottleneck, an **ultra-rapid method** aligns Quality Control with manufacturing needs, enables earlier release, and accelerates patient access to life-saving therapies

WHAT DID WE ACHIEVE

1. **Same-shift sterility** results for cell-based samples
2. Efficient, low-volume sampling of 0.1-2 mL
3. **Sensitivity & Specificity** equivalent to traditional methods

HOW DO YOU BALANCE YOUR NEED FOR SPEED WITH THE NEED TO LEAD RESPONSIBLY IN ADDRESSING URGENT HEALTHCARE CHALLENGES?

Our Offering

- ✔ Drastically reduce the time required to deliver your life-saving therapies to patients in need
- ✔ Preserve final therapeutic dose for patients *(by minimizing QC sampling requirements)*
- ✔ Rely on a proven method that is broadly applicable to current and future therapies

DISCOVER THE SCANRDI® CELL-BURST SOLUTION

CELL-BURST SOLUTION: A SCANRDI® SOLUTION FOR STERILITY TESTING OF CELL-BASED PRODUCTS WITHIN THE SAME SHIFT

SCANRDI®
CELL-BURST

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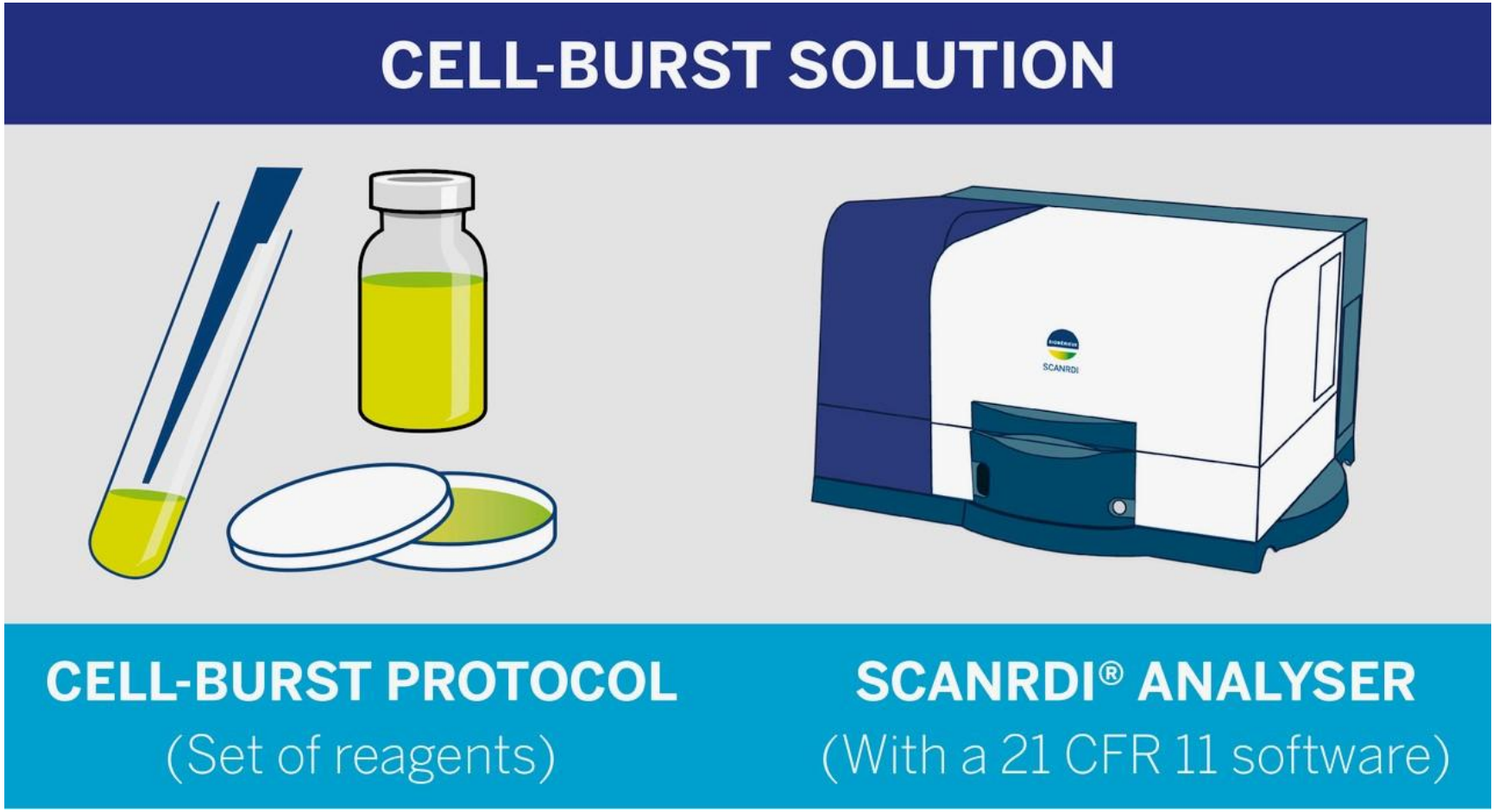
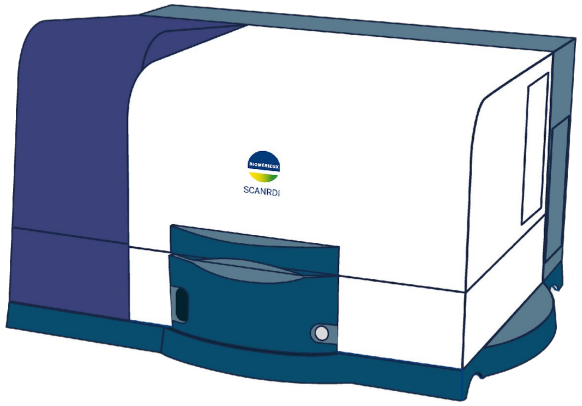
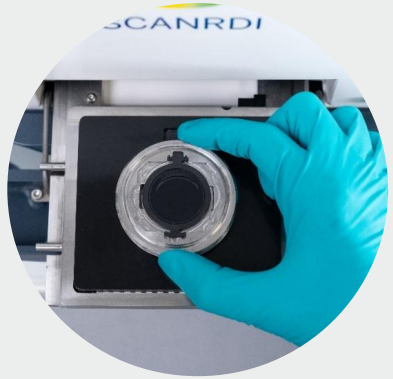


WHAT IS SOLID PHASE CYTOMETRY?



DIRECT DETECTION METHOD (NO GROWTH)



FILTRATION	FLUORESCENT LABEL	LASER SCANING

OUR VALUE

SAME-SHIFT STERILITY RESULTS

Results in less than 4-**6 hours**.

BROAD SPECIFICTY

- **Universal fluorescent** labeling
- Bacteria, yeast, and mold detection

PROVEN TECHNOLOGY

- Down to **1 microbe**/filtrable volume
- >200 compatible **small molecule** products

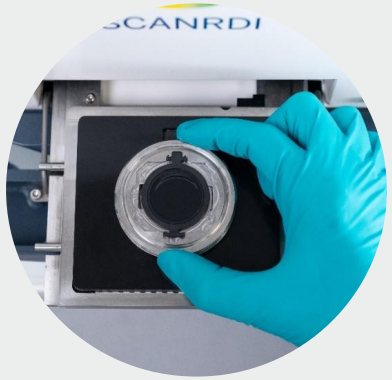
WHAT WE PROVIDE

CONTROL OVER YOUR MANUFACTURING PROCESS

CONFIDENCE IN YOUR COMPLIANCE

HOW DOES CELL-BURST TRANSFORM SOLID-PHASE CYTOMETRY FOR ULTRA RAPID STERILITY TESTING OF C&GT?

DIRECT DETECTION METHOD (NO GROWTH)



CELL-LYSIS
Patented workflow

FILTRATION

FLUORESCENT LABEL

LASER SCANING

VALIDATION APPROACH

EP 5.1.6
USP <1223>
PDA TR33

LIMIT OF DETECTION (LOD) ~ 400 TESTS *1/3 with CELL-BURST & 1/3 with broth & 1/3 with BACTALERT® 3D for equivalence demonstration*

SPECIFICITY > 400 TESTS
ability of the method to detect the required range of microorganisms

SUITABILITY > 150 TESTS
sample compatibility with the protocol

ROBUSTNESS & RUGGEDNESS ~260 TESTS
multiple instruments, multiple operators, different reagent batches, different days, 17 different protocol variations

BIOMÉRIEUX

WE CHECKED THE COMPATIBILITY OF CELLS DURING DEVELOPMENT AND *QUALITATIVE VALIDATION

JURKAT
CAR-T model used for development
Nominal quantity of 10^7, up to $5 \cdot 10^7$

CAR-T
Tested up to $6 \cdot 10^6$

DONOR LYMPHOCYTES T-CELLS
Tested up to $2 \cdot 10^7$

UNIT CORD BLOOD
Tested up to $2.4 \cdot 10^7$

DONOR LYMPHOCYTE INFUSION
Tested up to $2 \cdot 10^7$

MESENCHYMAL STEM (UMBILLICAL CORD)
Tested up to $2 \cdot 10^6$

Pharmacopeia Strains
(USP <71> / EP 2.6.27)

- **Clostridium sporogenes**
- ***Bacillus subtilis spizizenii***
- ***Aspergillus brasiliensis***
- ***Staphylococcus aureus***
- ***Candida albicans***
- ***Cutibacterium acnes***
- **Streptococcus pyogenes**
- **Pseudomonas paraeruginosa**
- **Micrococcus luteus**
- **Bacteroides vulgatus**

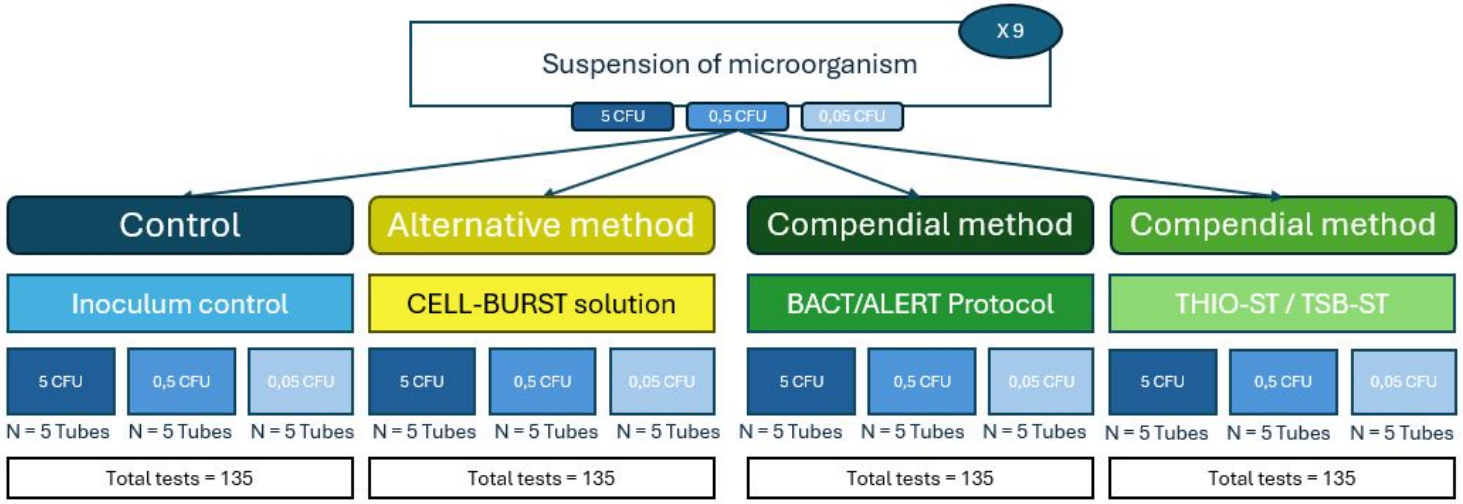
Other Relevant Strains
(e.g. EP 2.6.39 + pharma specific strains)

- **Escherichia coli**
- ***Moraxella osloensis***
- ***Bacteroides fragilis***
- ***Corynebacterium tuberculostearicum***
- ***Moraxella catarrhalis***
- ***Paracoccus yeei***
- ***Ralstonia pickettii***
- ***Penicillium expansum***
- ***Sphingomonas paucimobilis***
- ***Streptococcus pneumoniae***
- ***Penicillium chrysogenum***
- ***Staphylococcus epidermidis***

*not all tests were conducted with all cell types and/or strains

LOD & EQUIVALENCY

- **9 strains tested :** *A. brasiliensis, B. spizizenii, C. acnes, C. albicans, C. sporogenes, M. luteus, P. paraeruginosa, S. aureus, S. pyogenes*
- **Matrix:** Jurkat Cells at 10^7 per test
- **Acceptance criteria** *(statistical analysis):*
  - For each microorganism, 95% Confidence Interval (CI) of Most Probable Number (MPN) from the CELL-BURST Solution and each of the two other methods should overlap (PDA TR33).
  - Student T-Test of Non-Inferiority on MPN values between the CELL-BURST Solution and the other two methods (based on a 20% margin) should be significant (USP 1223).



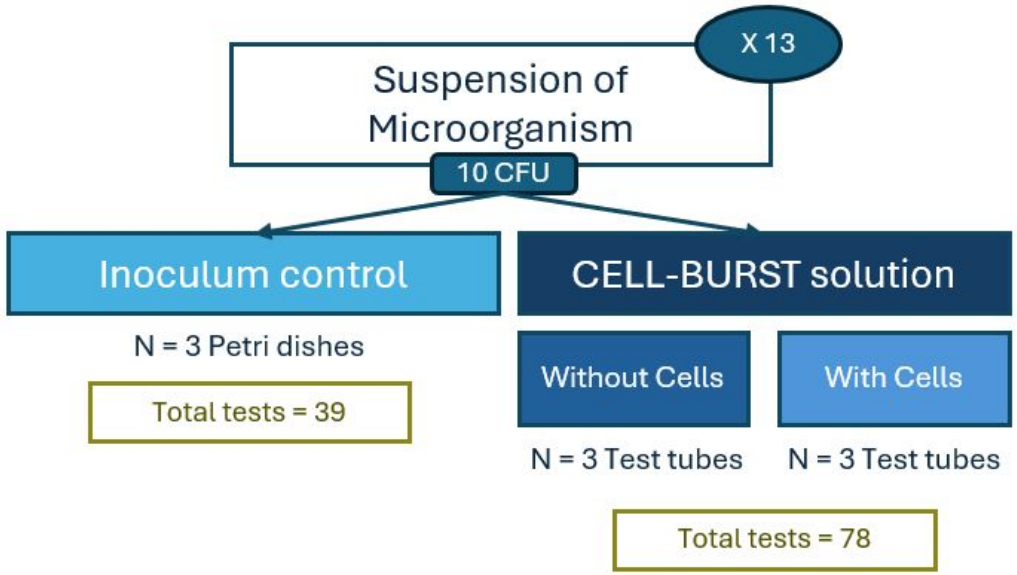
- **Conclusion**

- ✓ All conf. intervals for individual strains overlap
- ✓ → $\frac{GM_{CB}}{GM_{BACT}}$ = 1.506 and associated 95% CI Lower Limit = 0.889 > 0.8
- ✓ **Non-inferiority of the CELL-BURST solution vs. Traditional method is demonstrated**

- ✓ All conf. intervals for individual strains overlap
- ✓ → $\frac{GM_{CB}}{GM_{BACT}}$ = 1.648 and associated 95% CI Lower Limit = 0.985 > 0.8
- ✓ **Non-inferiority of the CELL-BURST solution vs. BACT/ALERT is demonstrated**

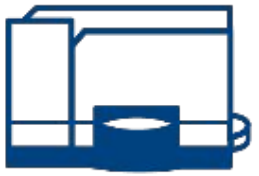
SPECIFICITY

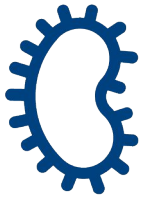
- **13 strains tested:** *E. coli, S. epidermidis, B. fragilis, B. vulgatus, S. paucibomilis, S. pneumoniae, P. chrysogenum, P. expansum, R. pickettii, Q. tuberculostearicum, M. catarrhalis, P. yeei, M. osloensis*
- **Matrix:** Jurkat Cells at 10^7 per test
- **Acceptance criteria**:
  - The presence of cells in the tested samples should not interfere with the detection of the target strains using the CELL-BURST method. Therefore, membranes tested with the CELL-BURST Solution and containing cells must yield a 100% positive result.
  - On membranes without cells, the CELL-BURST Method reagents must demonstrate their selective ability to lyse mammalian cells. Therefore, membranes tested under these conditions are expected to yield a 100% positive detection of the tested microorganism.
- **Conclusion :** CELL-BURST solution, **is capable of detecting a broad spectrum of microorganisms** listed in the compendia as well as common pharmaceutical environment isolates, both in the presence and absence of Jurkat cells.



RUGGEDNESS & ROBUSTNESS

- 2 instruments
- 2 operators
- 3 different reagent batches
- 3 different microorganisms tested in 5 repeats (Ruggedness)
- 9 different strains tested in 8 repeats (Robustness)
- Different testing conditions





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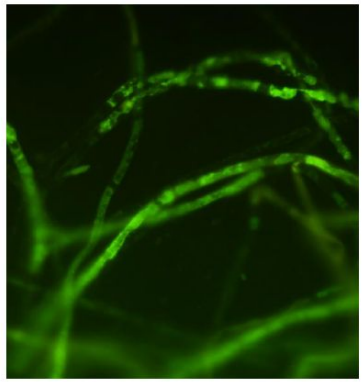
PDA J Pharm Sci Technol. 2023 Dec 7;77(6):498-513. doi: 10.5731/pdajpst.2022.012775.

A Rapid Sterility Method Using Solid Phase Cytometry for Cell-Based Preparations and Culture Media and Buffers

Mahsa Mohammadi [1], Aline Bauer [2], David Roesti [3], Hans-Joachim Anders [4]

Affiliations + expand

PMID: 37580128 DOI: 10.5731/pdajpst.2022.012775



Sterility testing of a Cell-based Product with new development of Solid Phase Cytometry (SCANRDI®)

European Microbiology Conference
Wien, 20. – 22. May 2025

18th ECA European Microbiology Conference Presentation by Dr. Anders Hans-Joachim

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BIOMÉRIEUX

ANNEX SLIDES

FOR OVER 60 YEARS,
EVERYTHING WE DO
IS GUIDED BY OUR PURPOSE

WE HELP MAKE THE WORLD A

HEALTHIER PLACE

We help make the world a healthier place.

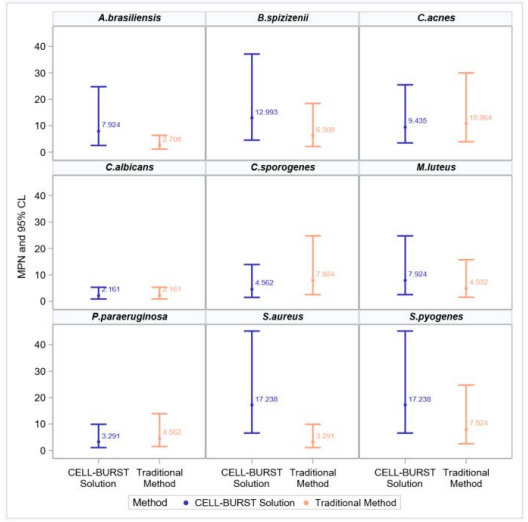
All around the world, our passionate team members are committed to **protecting patient safety** by providing manufacturers with reliable solutions to help guarantee the safety and quality of pharmaceutical products.

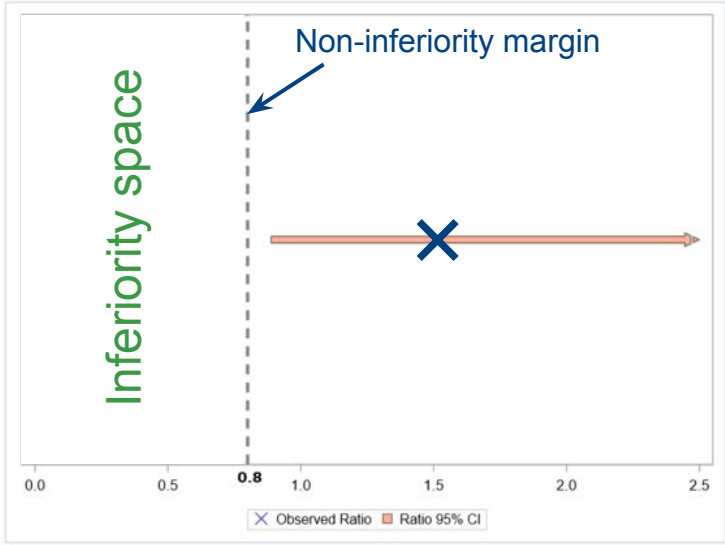
LOD & EQUIVALENCY RESULTS

Specific MPN Results for Strains

Output From Non-inferiority Test

CELL-BURST **vs.** TRADITIONAL METHOD





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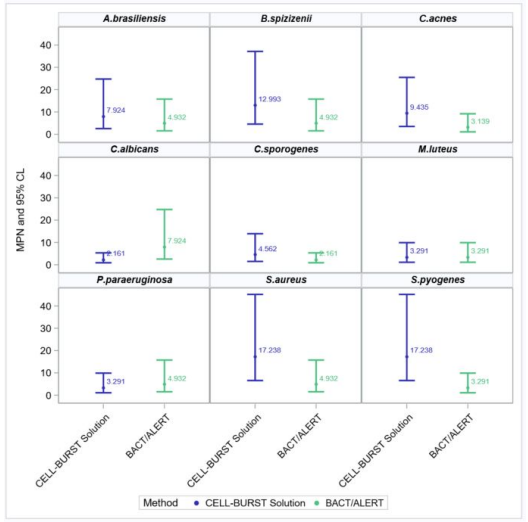

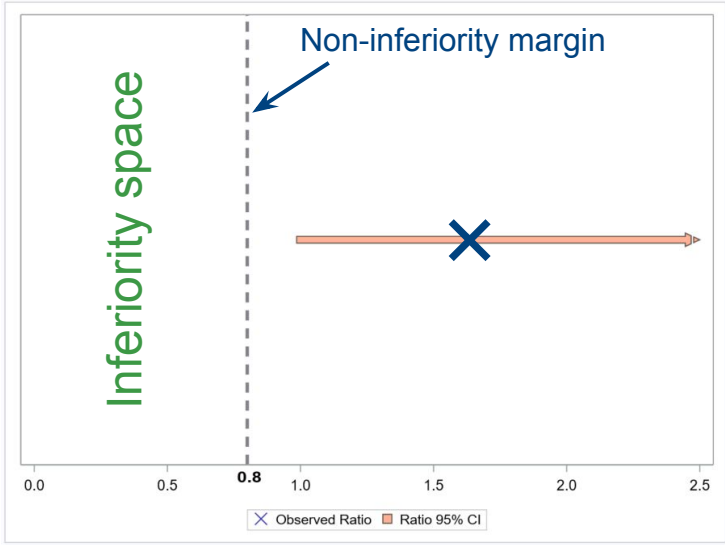

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