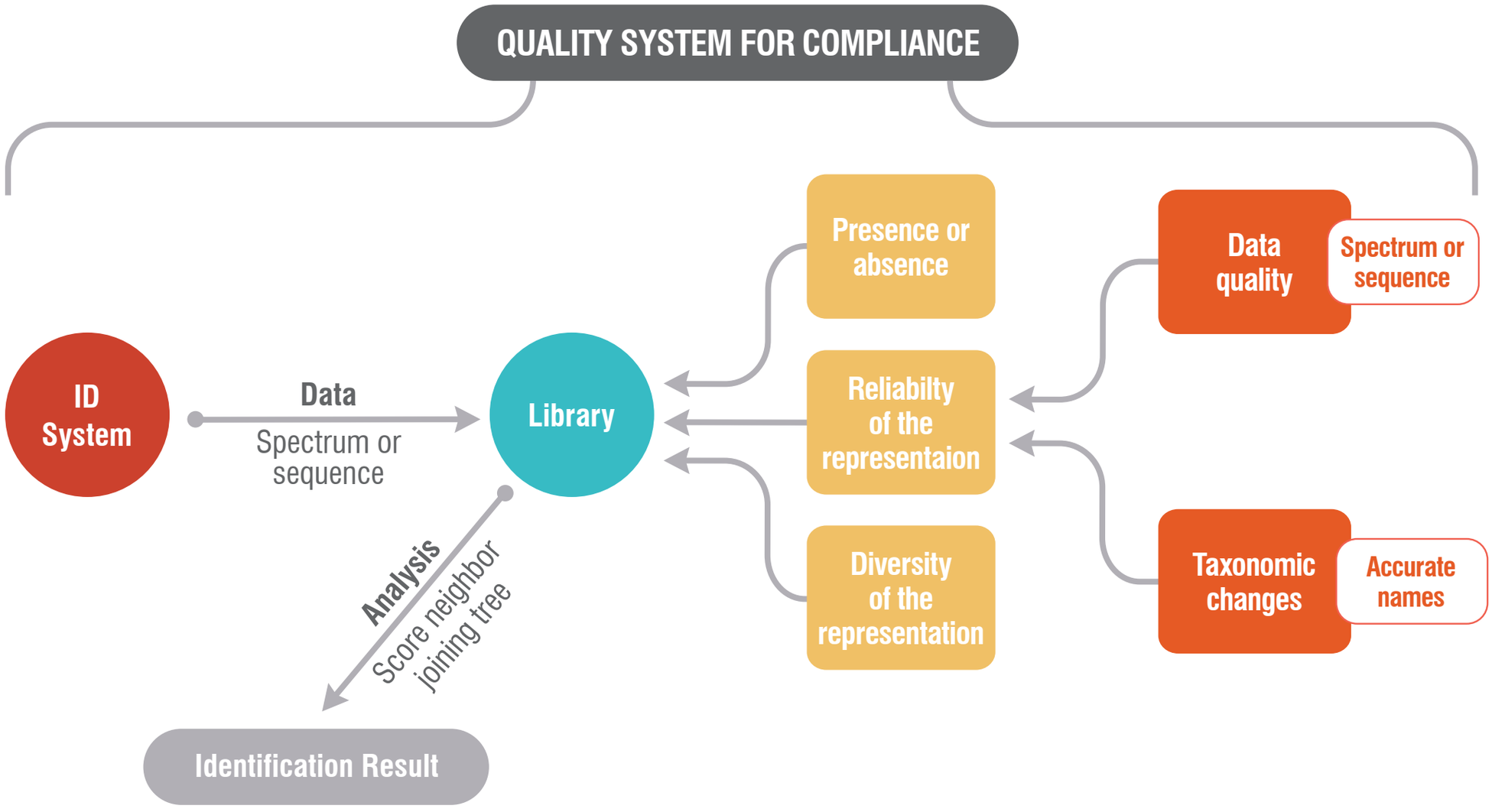
ACCUGENIX®

MICROBIAL IDENTIFICATION LIBRARY COMPARISON

charles river

Why Do Microbial Identification Libraries Matter?

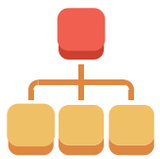


Maintaining Validated Compliant Libraries

What Does It Mean?

Updating

Being aware of taxonomic changes and renaming; ensuring accuracy of names



Expanding

Adding new species or organisms, growing the diversity of accurate identifications in the environment

Validating

Ensuring a qualified system maintaining industry regulations and compliance – reporting and tracking valid results

Qualifying

Proving accurate and consistent identifications are reported – generating an accurate identification is important regardless of the ID method or system used

How Is A Library Updated?

Initiate update

- Customer sample
- Library maintenance

Generate a new entry

- Obtain sequence in question
- Identify closely related sequences
- Obtain the published sequence

Modify an existing entry

- Has an old taxonomic name
- Is no longer valid
- Has a spelling mistake
- Has a sequence error

Review and Quality Verification

- Consistent with IJSEM or other peer reviewed journal defining species
- Species clusters with others in same genus
- Name and reference are confirmed as current accepted taxonomy

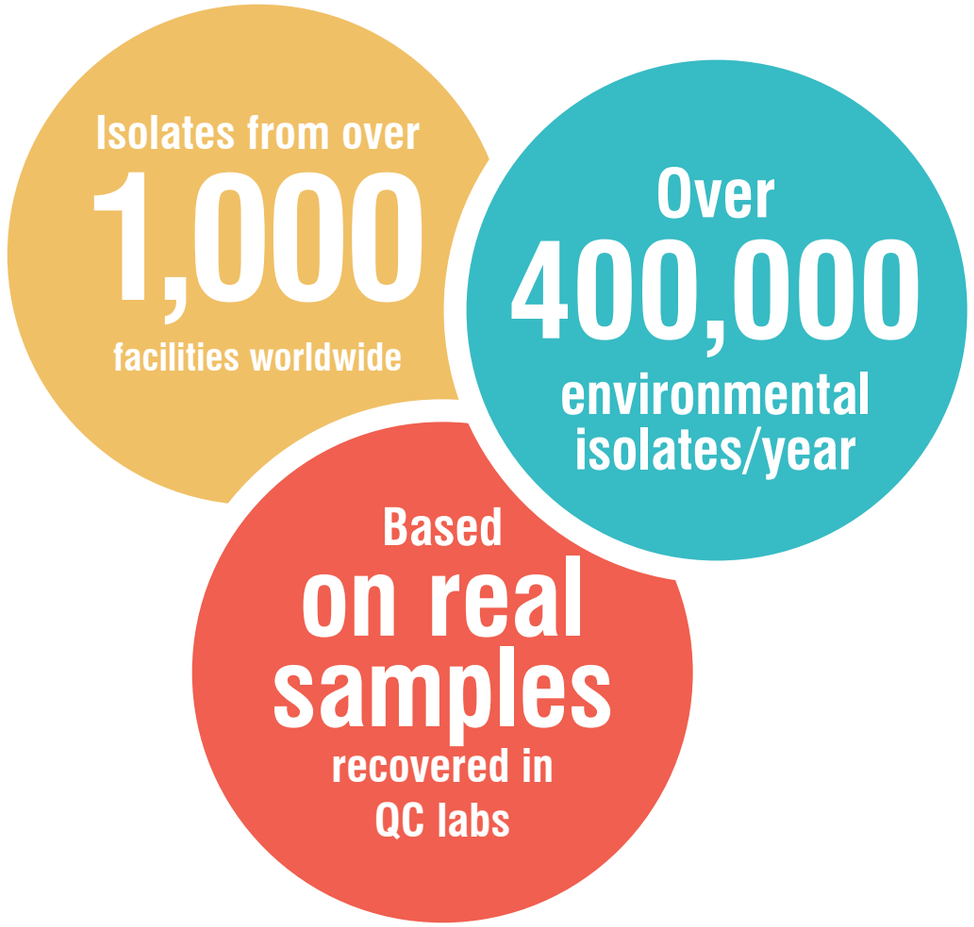
Valid entry and library release

- New library version created including all qualified entries since last version

Library Diversity

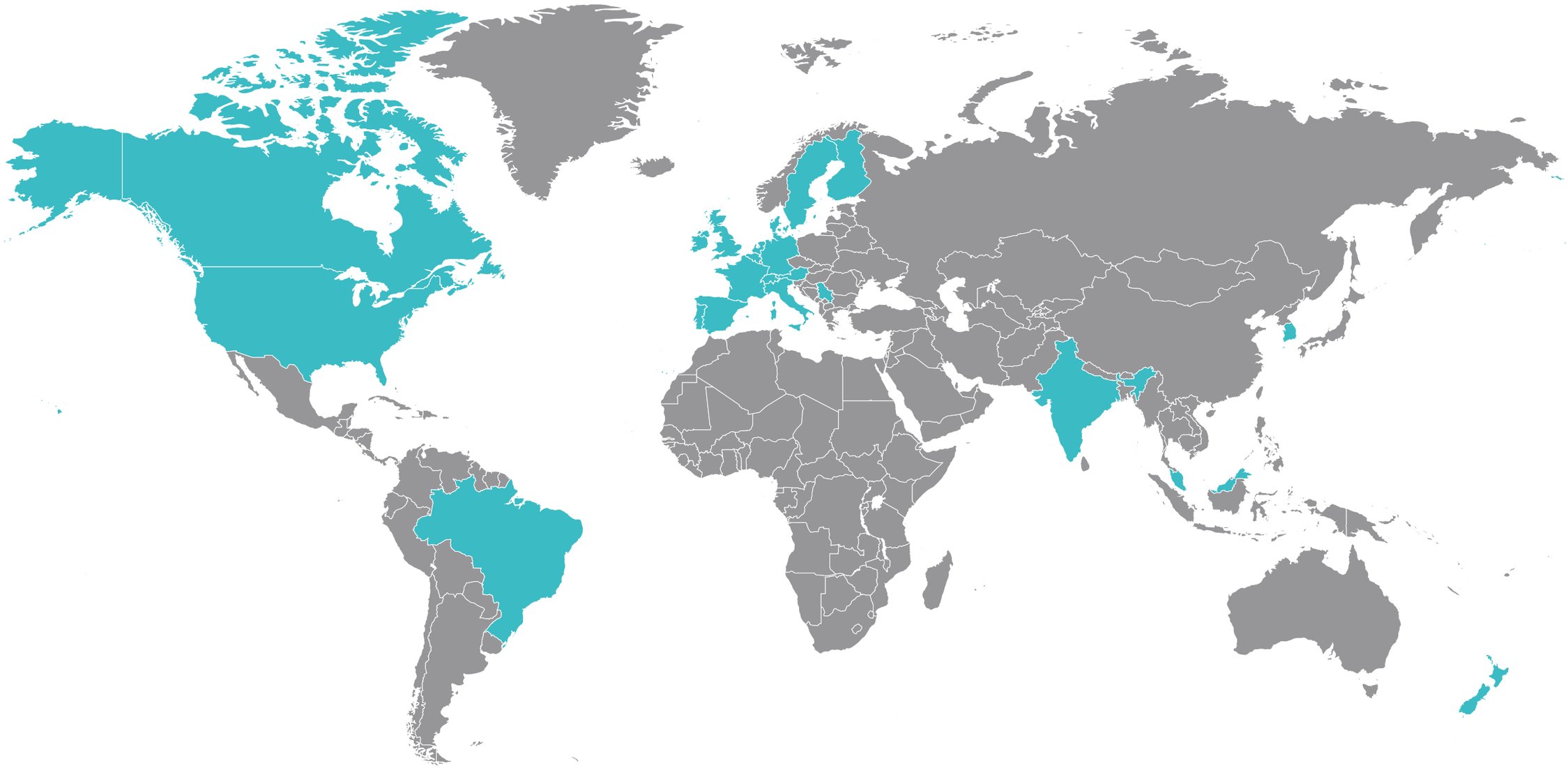
For all of these reasons we are able to create the largest, most relevant database for the industries we serve.

- Our database covers isolates from over 1,000 facilities worldwide
- Serving:
  - Biopharmaceutical
  - Medical device
  - Nutraceutical
  - Compounding pharmacy
  - Personal care and cosmetics
- Over 400K environmental isolates/year
- Our diversity and global vision enable us to expand our organism libraries based on real samples currently being recovered in QC labs around the world



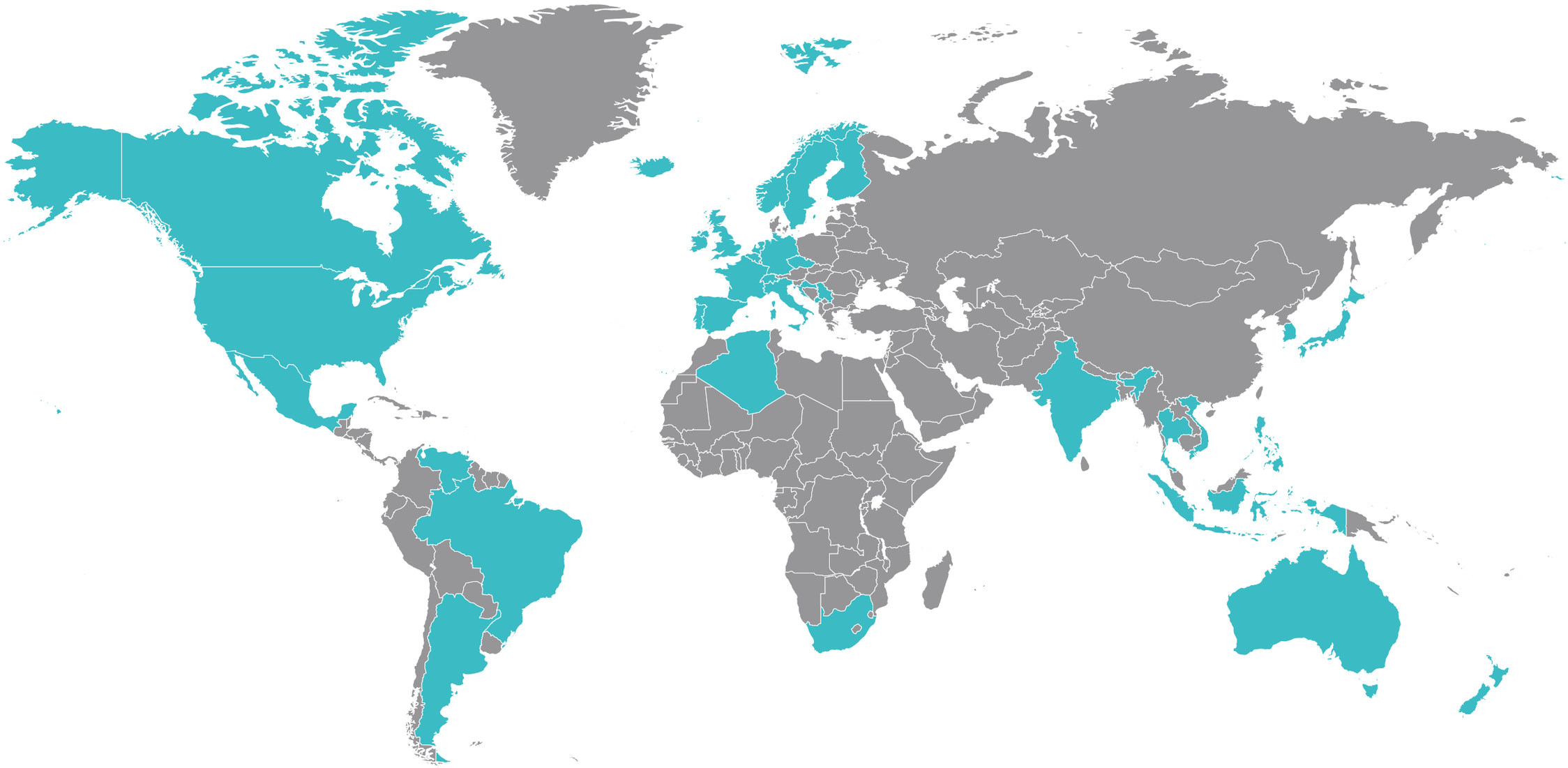
MALDI Library Global Diversity

Originating from 69 different states or regions; representing 21 different countries



Sequencing Library Global Diversity

Originating from 70 different states or regions; representing 38 different countries



Global Database

MICROBIAL SOLUTIONS' GLOBAL PRESENCE

9 Accugenix® labs currently, with additional sites planned for the future

Library Considerations

Using Accugenix® Outsourcing services or our Axcess® Insourcing solution builds confidence in your science and product quality and removes workload, time, and cost

Costs of

- Upgrades and requalification
- Revalidation
- Review
- Scripts
- New PQ

Accuracy

- Reliability
- Scientific validity
- Compliance
- Comprehensiveness

Customer need

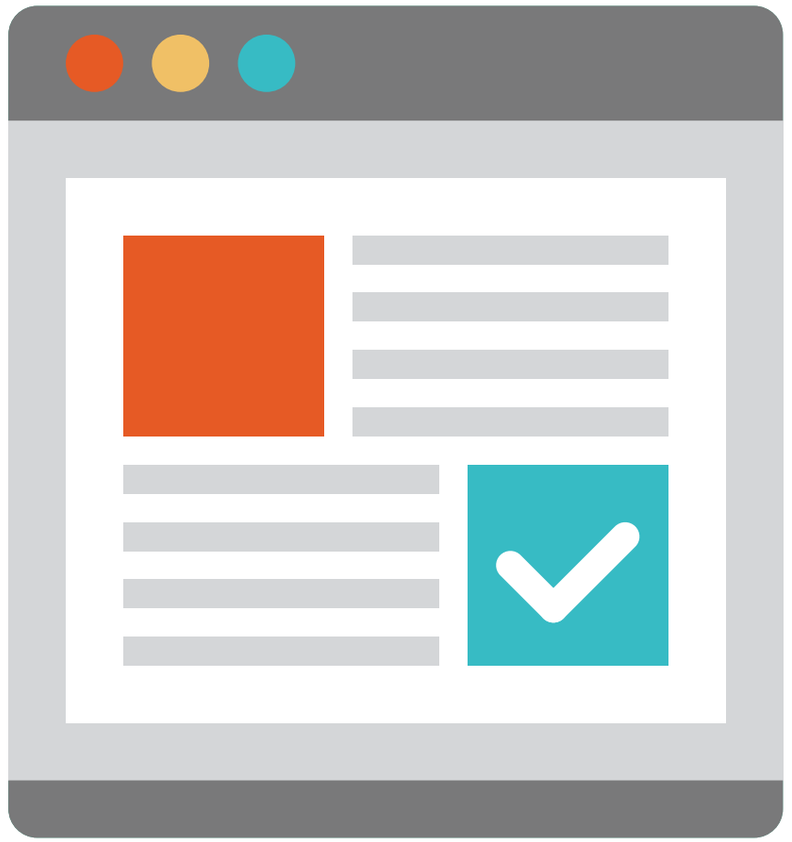
- Insourcing utilizing non-Charles River Laboratories systems means that updates are dictated by the manufacturer of the system and are not based on independent need, or customer need.
- Updates cost tremendous time and money and are not always beneficial or relevant for what the customer needs based on facility flora.
- Risk Assessments for internal library updates must be handled and performed by the customer when insourcing a non-Charles River system.

Analysis

- Dedicated resources and expertise to perform validation and updates.
- Trained data review specialist team – data interpretation
- Accuracy depends on the scientific method used to generate data and science used to interpret that data

Is Relevance Important?

Charles River is continually expanding our library coverage to ensure our customers will receive accurate, identifications that are not otherwise attainable using commercially available systems.



- Insufficient library coverage impacts the number of reportable results.
- Employing multiple commercial systems increases cost but doesn't guarantee a higher rate of species-level identifications.
- Library coverage must be reflective of the organisms observed in your environment.
- Accugenix® libraries are built in a quality environment and validated to ensure consistent performance and accuracy.
- Accugenix® libraries contain the most recent taxonomic names.
- If you find that your organism of interest is not included in our library, consult the List of Prokaryotic Names with Standing in Nomenclature (LPSN) website at www.bacterio.net. It is likely that the species is in the library but listed under a more recent taxonomic name.

No identification or inaccurate identifications are mainly due to missing relevant species in the database.

Is Relevance Important?

- Building libraries based on organisms frequency found during environmental monitoring directly impacts reportable accurate results.
- The Accugenix® Bacterial Library contains substantially more unique library entries than any other commercially available identification system.
- The current gold standard for microbial identification is DNA sequencing. However, the accuracy of genotypic systems is highly dependent on library coverage.
- For phenotypic and biochemical systems, gaps in library coverage are a considerable source of misidentifications.

Data Integrity

The data collected in the laboratory determines product quality and ensures products will be safe for the patients that we serve.

One key influence is the shift from paper-based data collection systems to fully integrated electronic data collection platforms with traceability from raw material to QC laboratory to final finished product. This shift has changed the way the industry operates and has allowed for great improvements in:

- product quality
- manufacturing capacity
- organizational efficiency

Electronic systems have also altered the way in which we generate and store data, and has impacted our compliance stance with world regulators around the integrity of that data.

The United States Food and Drug Administration (FDA) published a comprehensive guidance for the industry regarding current Good Manufacturing Practices (cGMP) around compliance with data integrity regulations in the laboratory and beyond.

Our Internal Process on Data Integrity

- Operates through automation, with no user intervention, and no opportunity for user intervention
- 21 CFR Part 11 compliant
- Fully validated using a Good Automated Manufacturing Practice (GAMP) version 5 compliant set of Software Development Life Cycle procedures
- Validation package is available for inspection in the context of a customer audits
- Regulatory requirements considered span FDA 21 CFR Part 11 and CGMP, EU Annex 11, MHRA (ALCOA+ data integrity), OECD-17, and ISO 9000 standards

Charles River's PDA Poster on Data Integrity in the Microbiology Lab

Ask Yourself…

As a laboratory professional in the industry, what questions should you be asking to ensure your electronic systems are up-to-date and compliant?

1. Does it take days to review stacks of lab notes and data?
2. Is manual data entry and review a waste of valuable time?
3. Have you found manual transcription errors that compromise your data integrity?
4. Is your data secure?
5. How do you track and trend your data?
6. How do you use your identification results?
7. How do you report your data?

Comparison Data

Charles River is committed to ensuring all of your important species are present in our validated bacterial library by routinely comparing differences in library performance for environmental isolates, analyzing the bacterial databases of six commercially available identification systems and comparing them to our proprietary bacterial 16S library for coverage.

Technology	Unique Bacterial Species Entries	Relevant Bacterial Species entries	Excluded Bacterial Species entries
Accugenix® Jun 2020	8150	4757	0
BioTyper 8.0.0.0	2250	1432	3325
MicroSeq v2013	1863	1577	3180
BioLog GEN III 2013	1530	1199	3558
VITEK MS SARAMIS KB V4.15	1136	974	3783
VITEK 2 v2009	428	406	4351

To learn more about Charles Rivers Microbial Identification Libraries and development visit, bit.ly/2ExqQtW

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