# EQASP

## EQA Sample Production Program

EQASP@1wa.org

oneworld ACCURACY®

ISO/IEC17043: 2010 Accredited

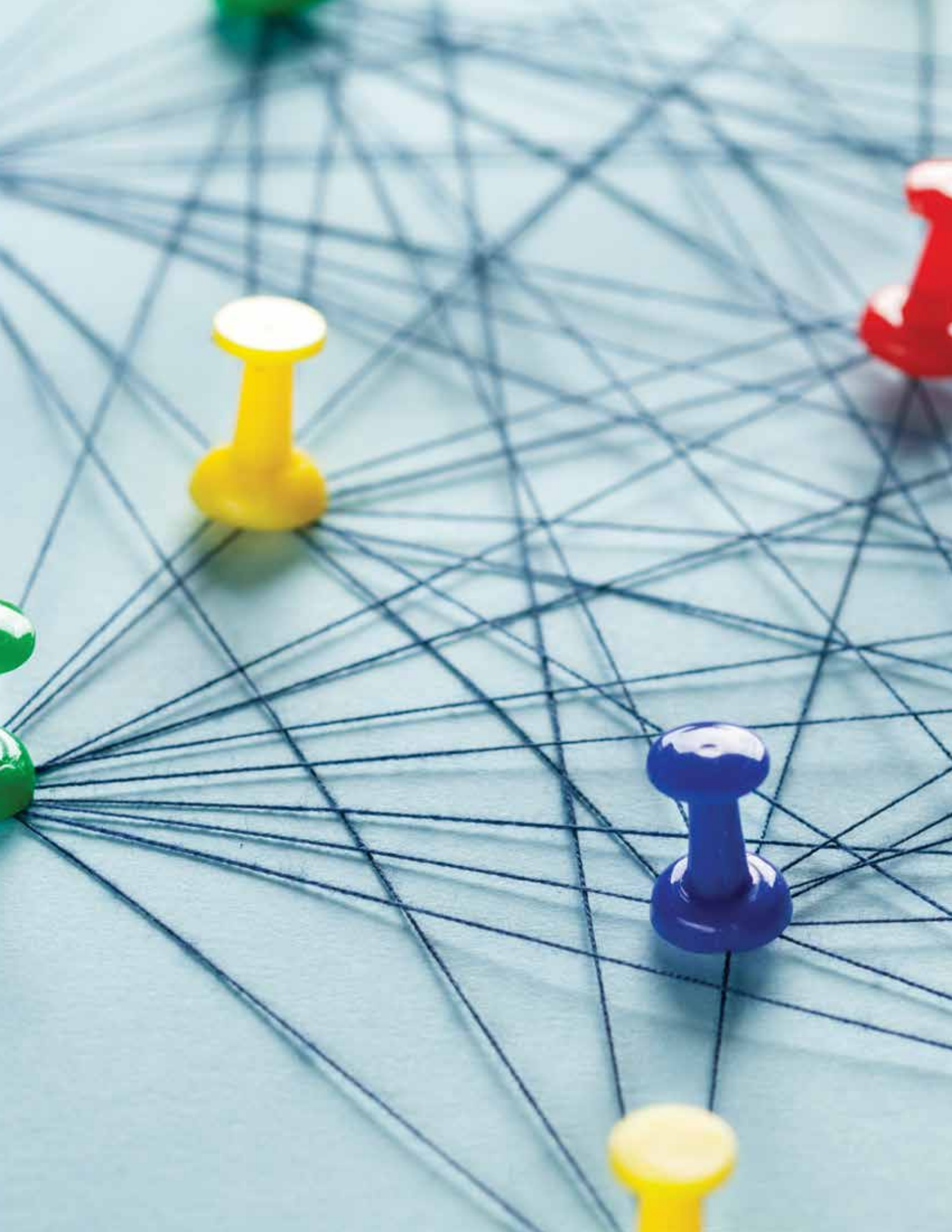
# COLLABORATIVE EQA

Oneworld Accuracy is a social enterprise group headquartered in Vancouver, Canada. We are guided by the conviction that accurate medical tests are a fundamental human right for all people in all countries as they enable doctors to make proper decisions, so patients receive proper care. We provide comprehensive, national, ISO/IEC17043 accredited external quality assessment (EQA) programs in Canada, the U.S. (CMS credentialed) and Europe.

We also act as the secretariat in the collaborative EQA model, which seeks to organize national, networked, collaborative, sustainable EQA programs in all countries. Public health stakeholders, typically National Public Health Agencies, National Reference Laboratories and Ministries of Health, assume the active role of EQA providers. They design and implement EQA programs that focus on their public health priorities which they manage on OASYS (Oneworld Accuracy System), an online EQA informatics system we develop, host and continually improve.

The collaborative EQA model is simple, powerful and successful.

Public health stakeholders in more than 50 countries have adopted the collaborative EQA model to start or improve national EQA programs.



# SUSTAINABILITY

EQA providers globally face the challenge of making EQA economically sustainable. A significant part of that challenge is the cost and complexity of procuring and transporting EQA samples from international sources.

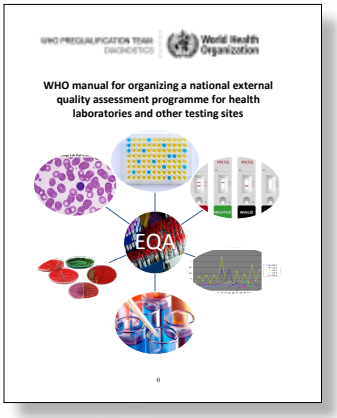
To specifically address that issue, we have developed EQASP – EQA Sample Production Program. EQA providers receive EQASP training to make their own EQA samples to the highest clinical standards for a set of EQA programs they manage on OASYS. EQASP enables EQA providers to:

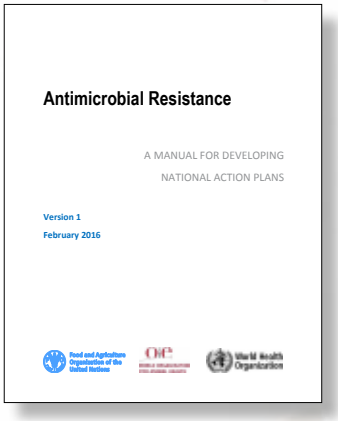
- eliminate or significantly reduce the cost of procuring samples
- eliminate the cost and complexity of importing samples
- make samples which better reflect local populations
- build in-country capacity
- commence operations quickly and efficiently with turnkey informatics
- scale operations with more participants and more programs

EQASP starts with bacteriology for several key reasons. Bacteriology EQA samples from commercial and international sources are expensive, do not travel well and are not welcomed at borders by customs services. Moreover, they are typically lyophilized for international travel. This means that they do not resemble or perform like clinical specimens. This compromises their EQA value, particularly as a meaningful assessment of the capability of a country's laboratory infrastructure to effectively detect antimicrobial resistance.

# BACTERIOLOGY

EQASP starts with two bacteriology programs designed for regional and national EQA providers, current and aspiring, who subscribe to the tenets in the WHO manual for organizing national EQA programs and who play a leadership role in developing or implementing national action plans for antimicrobial resistance in their countries.





Bacteriology Starter BACS436 involves five days of training at your site for three to five qualified staff members. They will learn how to produce six types of clinically-relevant simulated bacteriology EQA samples - urine, throat swabs, wound swabs, sputum, stool and fixed slides without background cells.

After gaining proficiency in managing your BACS436 EQA program, you have the option to progress to Bacteriology Advanced BACA436, which involves five days of training at your site or ours for three to five qualified staff members. They will learn how to produce four additional types of clinically-relevant simulated bacteriology EQA samples - whole blood, cerebrospinal fluid, joint fluid and fixed slides with background cells.

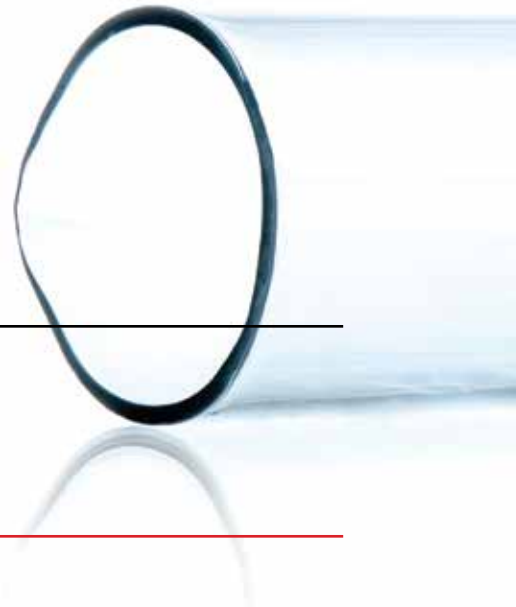
Each sample type in BACS436 and BACA436 will have a standardized set of microorganisms plus others that are endemic regionally. On completion of training, your staff will be ready to produce, QA, label, store and ship sample sets to your participants within a sophisticated, accreditable, EQA program fully managed by them on OASYS.

# MICHAEL A NOBLE MD FRCPC

**Medical Director, Microbiology EQA**

*I have dedicated more than 35 years of my professional life to improve the quality of microbiology testing worldwide through EQA, education and advocacy. I joined Oneworld Accuracy as Medical Director, Microbiology EQA as I believe the collaborative EQA model advances the principles underlying the WHO manual on national EQA programs. My first priority is to launch the EQASP starting with two bacteriology programs, both managed on a turnkey basis on OASYS. The goal is to empower your group to become an effective national EQA provider and leader supporting your country's national action plan for antimicrobial resistance. EQASP is collaborative and needs your support and input to meet its full potential. Feel free to contact me at mnoble@1wa.org.*

Dr. Noble is the founder and managing director of CMPT (Clinical Microbiology Proficiency Testing) and POLQM (Program Office for Laboratory Quality Management) at the University of British Columbia in Vancouver, Canada. He chaired the Technical Working Group for the WHO *manual for organizing a national external quality assessment programme for health laboratories and other test sites.* He chairs the Microbiology Working group for EQALM (European Organization for EQA Providers in Laboratory Medicine), currently comprised of forty-seven European and international EQA providers.



# BACTERIOLOGY STARTER

Bacteriology Starter BACS436 has 3 test events of 6 samples each calendar year, although you can elect to have more test events (e.g. four, six, twelve). BACS436 involves five days of training at your site for three to five of your qualified staff. Your staff will learn how to produce, QA, label, store and ship six types of clinically-relevant simulated bacteriology EQA samples including fixed slides without background cells and manage all EQA informatics using OASYS. Your participants will receive and test these eighteen EQA samples and submit clinical interpretations for all Gram stains.

## BACS436 MICROORGANISMS

| Urine | Sputum | Wound swab |
|---|---|---|
| *Enterobacter sp.* | *Haemophilus influenzae* | *Acinetobacter baumannii* |
| *Escherichia coli* | *Klebsiella pneumoniae* | *Corynebacterium jeikeium* |
| *Klebsiella sp.* | *Moraxella sp.* | *Enterococcus faecalis* |
| *Proteus sp.* | *Pseudomonas aeruginosa* | *Escherichia coli* |
| *Pseudomonas aeruginosa* | *Staphylococcus aureus* | *Klebsiella pneumoniae* |
| *Serratia sp.* | *Streptococcus pneumoniae* | *Pseudomonas aeruginosa* |
| *Staphylococcus epidermidis* | | *Staphylococcus aureus* |
| *Staphylococcus saprophyticus* | | *Streptococcus pyogenes* |

Gram stain  Culture  Culture + AST  Culture + AST + Gram stain

| Sample | Test Event 1 | Test Event 2 | Test Event 3 |
|---|---|---|---|
| A | Urine | Urine | Urine |
| B | Sputum | Sputum | Sputum |
| C | Wound swab | Wound swab | Wound swab |
| D | Throat swab | Throat swab | Throat swab |
| E | Stool | Stool | Stool |
| F | Fixed slide | Fixed slide | Fixed slide |

| Throat swab | Stool | Fixed slide (no background) |
|---|---|---|
| *Moraxella sp.* | *Campylobacter jejuni* | Fixed bacteria from BACS436 |
| *Streptococcus agalactiae* (Group B Strep) | *Escherichia coli* | |
| *Streptococcus dysgalactiae* | *Escherichia coli* O157 | |
| *Streptococcus equisimilis* (Group C Strep) | *Salmonella enterica* | |
| *Streptococcus pyogenes* (Group A Strep) | *Shigella flexneri* | |
| *Streptococcus salivarius* | *Shigella sonnei* | |
| | *Staphylococcus aureus* | |
| | *Yersinia enterocolitica* | |

# BACTERIOLOGY ADVANCED

Bacteriology Advanced BACA436 builds upon proficiency gained from Bacteriology Starter BACS436 so you can provide a more advanced EQA program for your larger microbiology laboratories. BACA436 has 3 test events of 6 samples each calendar year, although you can elect to have more test events (e.g. four, six, twelve). BACA436 involves five days of training at your site or ours for three to five of your qualified staff. Your staff will learn how to produce, QA, label, store and ship four additional types of clinically-relevant simulated bacteriology EQA samples - cerebrospinal fluid, joint fluid, whole blood and fixed slides with background cells - and manage all EQA informatics using OASYS. Simulated CSF and joint fluid are modest variations from the simulated urine samples covered in BACS436. Simulated whole blood and fixed slides with background cells are more complex and will require advanced technical skills. Your participants will receive and test these eighteen EQA samples and submit clinical interpretations for all Gram stains.

## BACA436 MICROORGANISMS

| Whole blood | Cerebrospinal fluid | Joint fluid |
|---|---|---|
| *Bacteroides sp.* | *Cryptococcus neoformans* (not bacterial) | *Neisseria gonorrhoeae* |
| *Enterobacter sp.* | *Neisseria meningitidis* | *Pseudomonas sp.* |
| *Enterococcus sp.* | *Staphylococcus aureus* | *Salmonella sp.* |
| *Escherichia coli* | *Streptococcus agalactiae* | *Staphylococcus aureus* |
| *Klebsiella sp.* | | *Staphylococcus epidermidis* |
| *Propianobacterium sp.* | | |
| *Pseudomonas sp.* | | |
| *Salmonella sp.* | | |
| *Staphylococcus aureus* | | |
| *Staphylococcus epidermidis* | | |

Gram stain  Culture  Culture + AST  Culture + AST + Gram stain

| Sample | Test Event 1 | Test Event 2 | Test Event 3 |
|---|---|---|---|
| A | Urine | Whole blood | Urine |
| B | Sputum | Cerebrospinal fluid | Sputum |
| C | Wound swab | Joint fluid | Wound swab |
| D | Throat swab | Throat swab | Whole blood |
| E | Stool | Stool | Cerebrospinal fluid |
| F | Fixed slide | Fixed slide | Fixed slide |

Fixed slide with background cells

Fixed bacteria from BACS436 and BACA436

Background cells include

- red blood cells
- white blood cells
- epithelial cells
- crystals

# REQUIREMENTS

Laboratory requirements for Bacteriology Starter BACS436 and Bacteriology Advanced BACA436 are minimal. You will need a segregated sample production area with sufficient bench space and workstations for your staff (minimum 14 $m^2$) and a segregated shipping area (minimum 20 $m^2$). Since you will be handling live pathogenic bacteria, adherence to biosafety procedures and good laboratory practices are required to reduce the risk of acquiring and transmitting infection.

Your staff should be certified laboratory technologists with a minimum of three years' microbiology experience with proficiency in Gram staining, bacterial culture, isolation, identification, typing and antimicrobial susceptibility testing. They should also have EQA experience as participant and / or provider and working knowledge in a Quality Management System. Ideally, your staff works well as a quality driven team under a designated experienced microbiology supervisor.

It is strongly recommended that you organize a Microbiology Advisory Board comprised of three or more qualified members. This advisory board will provide on-going design of BACS436 and BACA436, review participant performance, furnish guidance for continuous quality improvement and provide leadership to the Ministry of Health and international stakeholders on the impact of EQA performance on the AMR national action plan.

## Equipment for BACS436

Autoclave
Safety centrifuge
Freezer (-15 to -25°C)
Fridge (2 to 8°C)
Incubator (37°C)
Microscope (with 100x objective)
Microwave oven (dedicated)
Pipettes (20 µL - 200 µL - 1000 µL) or dropper
Erlenmeyers (500 mL - 1 L - 2 L)
Glass bottle screw caps (250 mL - 500 mL - 1L)

## Additional equipment for BACA436

Biosafety cabinet (BSL-II)
Deep freezer (-60 to -80°C)
Multihead pipettes (1 mL)
Spectrophotometer

## Consumables

15 mL cone tubes
Eppendorfs
Inoculation loops
Petri dishes
Screw caps 2 mL tubes
Slides
Swabs

## Reagents

Gram strains
Growth media (Blood agar, Mueller Hinton, Chocolate)
Immersion oil
Non-human serum

## Shipping

Freezer for gel packs
Peanut filling station
Storage for empty boxes
Storage for shipping-ready boxes
Tables for set packing
Triple packaging material

# GET OPERATIONAL

EQASP has compelling economics. If you have 15 or more bacteriology participants, EQASP will be more cost-effective than procuring samples from outside sources. We have a one-time fee to cover travel expenses for our trainers. We also ask for an annual informatics fee for each EQA subscription, within your budget, to help defray the cost of developing, hosting and continuously improving OASYS as a shared informatics resource. This funding model promotes EQA sustainability while maintaining the highest clinical standards.

Getting started is simple. Your group can be operational in three months or less:

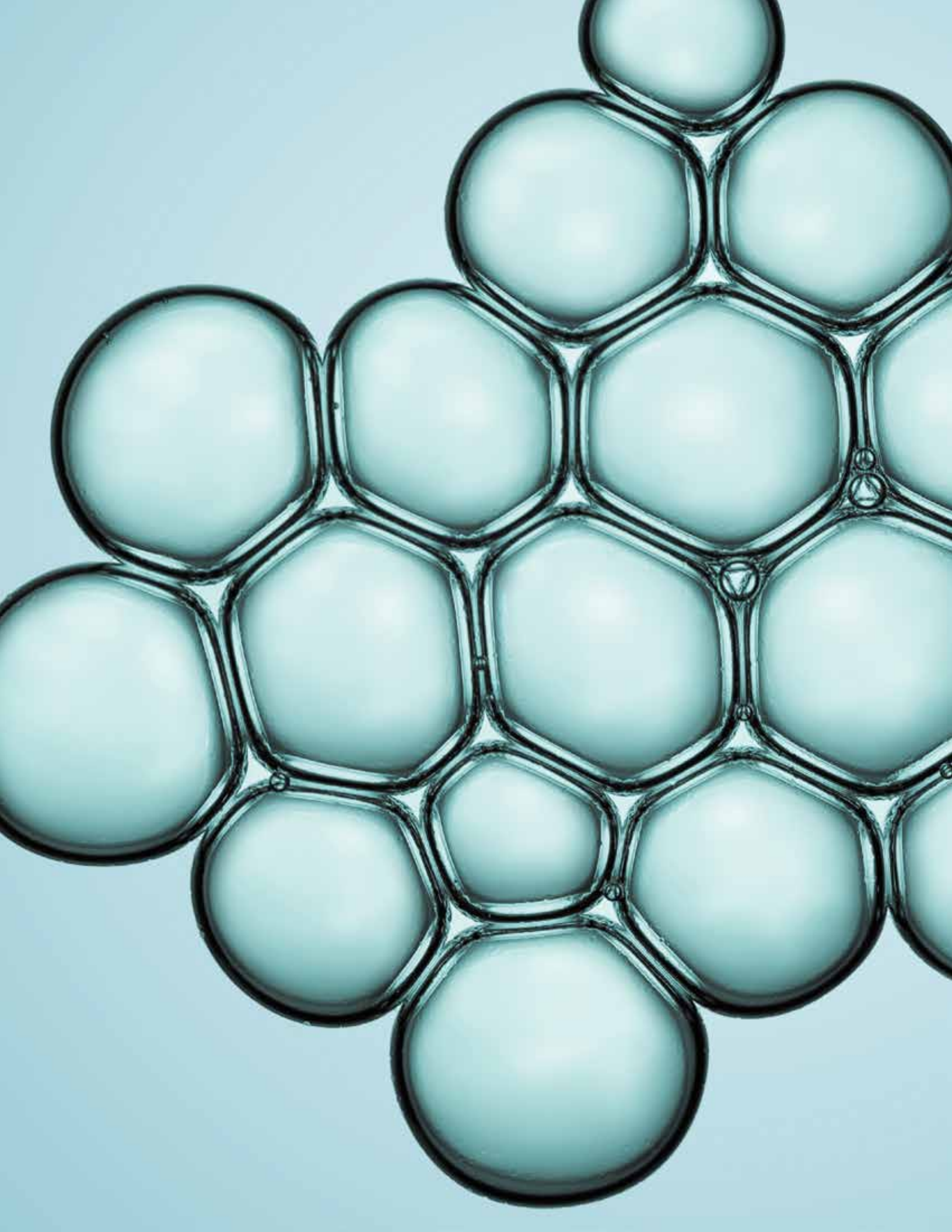
| | | |
|---|---|---|
| 1 | Contact us at EQASP@1wa.org and complete the EQASP Checklist | Day 1 |
| 2 | Schedule training for Bacteriology Starter BACS436 at your site | Day 2 |
| 3 | Conduct five days BACS436 training | Day 30 + |
| 4 | Review and approval of your SOPs and protocols | Day 30 + |
| 5 | Form your Microbiology Advisory Board | Day 30 + |
| 6 | Prepare your EQA samples | Day 40 - 60 |
| 7 | Verify your EQA samples with us and cross-checked by another group | Day 60 - 80 |
| 8 | Start your first BACS436 test event | Day 90 |

The five-day training session for Bacteriology Starter BACS436 is broken into:

- Production modules, which cover how to make clinically-relevant simulated bacteriology samples for urine, sputum, throat, wound, stool and slides for Gram staining.

- Management modules, which cover how to develop a national microbiology EQA program and document its operation, form and organize a Microbiology Advisory Board, prepare case histories, QC sample production, ship samples, develop evaluation criteria, organize test events, conduct root cause analyses and manage corrective actions.

- Informatics modules, which cover how to use OASYS to register participants and manage their subscriptions using the Sales Console, manage their results submission using Test Event Dashboard, interpret performance reports and participation statistics reports and evaluate performance using REP Console.



# EQASP

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CREATING
EFFECTIVE AMR SURVEILLANCE
WITH SUSTAINABLE EQA

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