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CMPT and our Commitment to a Quality Commitment

By Dr. Michael Noble

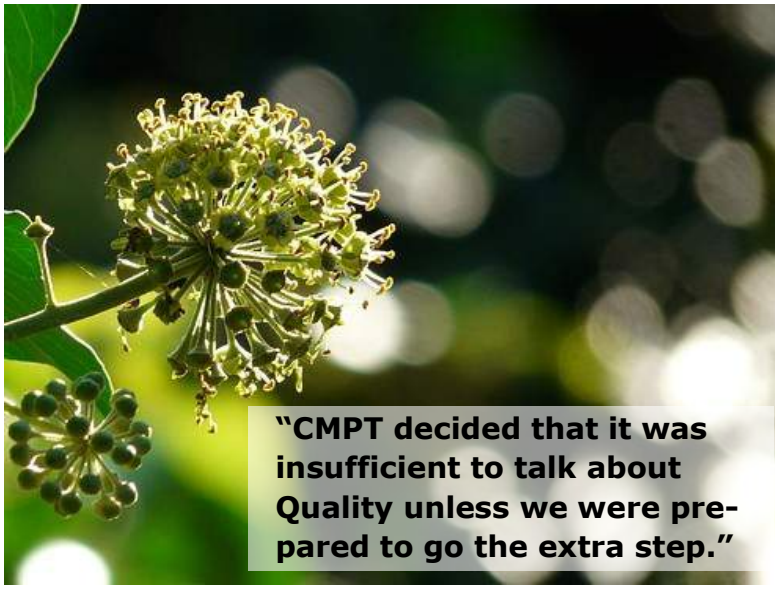
Many involved in Canadian healthcare services understand that Canada's healthcare system is unique.

In most jurisdictions around the world (United States, Europe, Australia, and New Zealand), it is a national mandate that medical laboratories *and* their Quality Partners all demonstrate a professional commitment to Quality. Just as hospitals and laboratories are audited (accredited) to ensure that standards are met, so too are most of the quality partners.

In many countries, Accreditation Bodies are expected to meet the ISO standard 17011 (*Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*) or as in the case of the United States the national requirements of Clinical Laboratory Improvement Act (and Amendments).

Similarly, medical device suppliers need to meet the requirements of ISO13485 (*Medical devices -- Quality management systems -- Requirements for regulatory purposes*) or the requirements of the Food and Drug Administration. Universities and other teaching institutions are expected to meet national standards for quality and competence. And similarly, the case is made that proficiency testing programs must meet certain expectations, which in the United States again requires the Clinical Laboratory Improvement Act and in the rest of the world includes ISO 17043:2010 (*Conformity assessment - General requirements for proficiency testing*). It is society's way of ensuring to the extent possible that not only institutions that take on the primary professional responsibility of healthcare meet expectations of Quality, but so too should the organizations that monitor and guide that special level of highest Quality.

In Canada however, these rules may not apply, not at least at the national level. Some say this is because our Fathers of Confederation decided in 1867 that



"CMPT decided that it was insufficient to talk about Quality unless we were prepared to go the extra step."

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health should be under the jurisdiction of provinces rather than the federal government. However, that does not explain why most provinces have never taken on the responsibility to require all organizations involved in healthcare rise to that higher level of Quality nor does it explain why in nearly 150 years of Canadian nationhood have politicians not moved to change the legislation. In the minds of some, perhaps many, the lack of a federal mandate would appear to leave a potential Quality gap**,** which some organizations have addressed through voluntary inspection and accreditation.

In 2003, CMPT decided that it was insufficient to talk about Quality unless we were prepared to go the extra step. Using the tools that were available at the time, we undertook the responsibility of voluntary certification to the international standard ISO9001:2000/2008 (*Quality Management*) through the process of external audit. We were the first proficiency testing organization associated with healthcare in Canada to undergo that extra measure of confidence. We undertook this step first and foremost to ensure that we were seen to be meeting the highest level of Quality awareness and Error prevention.

As much as laboratories and accreditation bodies with whom we worked reported their confidence in our commitment to Quality, starting in 2012, we decided that it was time to extend the voluntary audit process. Following a thorough review we decided it would be appropriate to take on the additional commitment of auditing ourselves against the accreditation standard ISO 17043:2010.

This decision was not made lightly because the increase in rigour that would be required would mean additional commitments for time, energy, and finances. Nonetheless, after a year of investigation we decided that going for the additional recognition was the best way forward.

ISO 17043:2010 is a newly designed international standard specifically intended to address the activities associated with proficiency testing programs. Using common Quality terminology, it is a standard that is "fit for purpose". In addition, it is closely related to a suite of laboratory associated standards including ISO17025:2005 (*General requirements for the competence of testing and calibration laboratories*) and ISO15189:20012 (*Medical laboratories – Requirements for Quality and competence*) which means that it is a standard to which the laboratories with whom we work could relate.

Any medical laboratory that achieved the requirements of ISO15189:2012 or any water bacteriology laboratory that has achieved the requirements of ISO17025:2005 would immediately understand the level of Quality to which we aspired.

"We are now within an elite group of international proficiency testing bodies that have gone the extra mile … to demonstrate their absolute commitment to their customers."

CMPT and ISO/IEC 17043

With voluntary accreditation, we have the opportunity to select our assessor and we chose the American Association for Laboratory Accreditation (A2LA) as the most appropriate. They are known worldwide, they have already assessed other medical laboratory associated proficiency testing bodies, and are well recognized for their objectivity and completeness.

After having gone through our inspection and completed the noted recommendations, we have now received our certification of accreditation. By this recognition we are now within an elite group of international proficiency testing bodies that have gone the extra mile, some by requirement and some voluntarily, to demonstrate their absolute commitment to their customers throughout the healthcare system.

It is important to note that we are not the only, or even the first organization in Canada to have taken on this extra Quality measure. That honor goes to the laboratory assessment team in Ontario, initially known as the Quality Management Programme- Laboratory Services (QMP-LS) and now known as the Institute for Quality in Laboratory Medicine (IQLM) who underwent their first audit in 2012. It is also important to note that other programs are looking at following suit over the next year or years.

As a PT/EQA focused standard, ISO17043:2010 looks very intently at the laboratory techniques, quality control, quality management, and statistical management essential for supplying consistent and reliable PT/EQA samples. This close scrutiny helps CMPT in producing better samples. It will reinforce our quality foundation as we move forward in meeting the needs of our current clients and broadening our scope with new products.

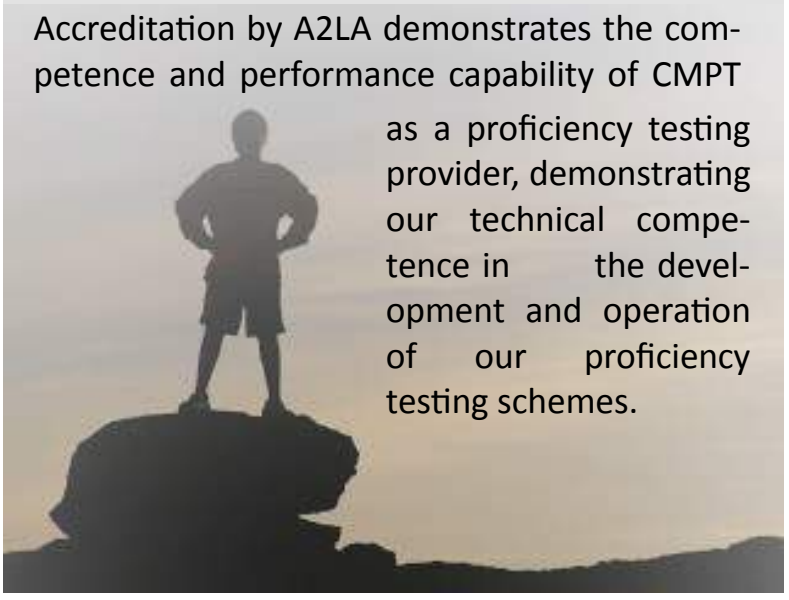
Some argue that some areas in which ISO 17043:2010 may yet need to develop, these areas are related to customer satisfaction. This is an arena very important to CMPT and one in which we have made measurable improvements through our 12 year application of ISO9001. It is for that reason that we have decided that for the time being we will continue to work with our ISO9001assessors (Standards Australia International) and the newest standard version ISO9001:2015.

Quality Management through all its facets can and probably should be a regulated requirement in healthcare everywhere in the world, including Canada. It is not, in our opinion, sufficient to accept the absence of a national standard as either appropriate or tolerable. In its absence, we have decided to take a step forward to meet the best international standard on a volunteer basis. It is our Commitment to a Healthcare Quality Commitment.

CMPT ISO/IEC 17043 accreditation

We are happy to announce that we are now accredited to ISO/IEC 17043:2010 *General Requirements for Proficiency Testing* as a Proficiency Testing (PT) provider by A2LA.

Accreditation by A2LA demonstrates the competence and performance capability of CMPT as a proficiency testing provider, demonstrating our technical competence in the development and operation of our proficiency testing schemes.



Ergonomics of Pipetting

By Suhanya Bhuvanendran—CMPT's Safety Officer

Manual pipettes are one of the most used pieces of equipment in laboratories of all disciplines and can be a cause for work-related strain injuries.

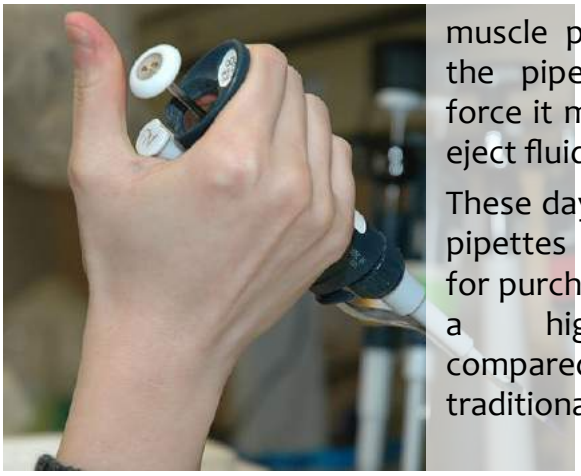
You have used a manual pipette on the laboratory bench regularly for a few minutes up to a few hours and may not have felt any lingering effects from this task. One day, you go home with a sore wrist, or a sore elbow, or maybe even a sore neck and attest it to a stressful day at work. Slowly, the sore spots start to feel progressively painful and you start wondering how to stop the pain and continue to work.

Manual pipettes are one of the most used pieces of equipment in laboratories of all disciplines and can be a cause for work-related strain injuries. A strain can be caused by overstretched muscle or tendon or due to partial or a complete tear of muscle or tendon. Natural body positions can be strenuous, if the position is held for a prolonged time and can cause musculoskeletal discomfort. Therefore, the task of traditional pipetting, which does not involve natural body postures or movements, can accelerate muscle fatigue and cause musculoskeletal disorders (MSDs).

When pipetting is done repetitively and for many hours, it can exacerbate strain on muscles and cause repetitive strain injuries (RSI). Thumb and fingers, palm, wrist, forearm, elbow and shoulders are the most affected during pipetting and are most likely to suffer from musculoskeletal disorders (MSDs), specifically repetitive strain injuries (RSI).

RSI is a type of musculoskeletal injury that results from combined effects of repetitive work and pace of work, poor posture, muscle force used for repetitive movement, inadequate rest, vibration, temperature, etc. Although repetitive work demands more muscular effort, and therefore longer recovery time between tasks, the nature of repetitive work itself does not allow for sufficient muscle recovery. This, in turn, exerts more force on some muscles than others causing muscle fatigue or strain, thereby injuring the muscle. Even in non-repetitive scenarios, thumb motions require a lot of force (4 kg[1]) to eject tips from the pipettes. This puts a lot of pressure on the tendons, ligaments and muscles in the hand and can cause thumb tendinitis and tenosynovitis. Evidence suggests that at least 1 in 10 Canadians are affected by repetitive strain injuries (RSI).

To reduce risk of musculoskeletal discomfort and/or injuries, the employee must carefully consider the task and take into account employee's body and elbow position, any previous episodes of muscle pain or injury, the pipette and the force it may require to eject fluid and the tip.



These days, ergonomic pipettes are available for purchase, albeit for a higher cost compared to the traditional pipettes. There are also electronic pipets available that have buttons that require lighter touch, programmable repetitive ejections, motors to control the plunger motion, etc. These traits can help eliminate the use of excessive force by muscles, ligaments and tendons and prevent muscle injuries. While some laboratory personnel may be deterred by the higher costs of ergonomic and electronic pipettes, the cost of lost working hours when an employee is injured, lowered productivity, workers' compensation costs, delay in completion of work and resulting lost opportunities can be more expensive to the employer. McGee et al reported that "MSDs cost Canada over $20.6 billion" in 2005[2].

Ergonomists suggest proper posture in helping to prevent MSD:

1. Shoulders: Shoulders should be in line with the hips, and not bent.
2. Legs: Legs should rest comfortably directly in front of the body
3. Arms: Pipette and supplies that need to be accessed repetitively or frequently should be within easy reach of forearms, which should be at 90° to the body. Things that need to be accessed regularly can be placed within the reach of the arm. The forearm should not be held in palm up (supinated position) for too long. This can affect thumb, fingers and wrist.
4. Wrist: The wrist should be relaxed, comfortable and in line with the forearm.
5. Fist: Holding a pipette tightly for a prolonged period of time could result in muscle fatigue in the hand, wrist and fingers[3]. Where possible, use pipets that have a hook, which enables the pipette to rest on the finger/hand and allows for the hand and wrist to be relaxed. A proper sized pipette that fits the hand can help alleviate some pressure on the wrist.
6. Thumb: Continuous or repetitive pressure on thumb can be alleviated by using pipettes that require lighter touch (i.e. electronic buttons) or have contoured or large, rounded plungers to accommodate the thumb. The thumb should be able to rest easily on the plunger knob for aspiration or dispensing actions. These pipettes should also operate smoothly and requires less force for ejection than traditional manual pipets. The controls should be within the reach of the thumb to avoid thumb muscles extending too much.
7. Breaks: Allow for small breaks in between repetitive tasks for muscles to recover. Task rotation, alternating hands between activities and allowing mini-breaks in repetitive motion can help muscles to recover between tasks.

While knowledge of ergonomics is essential, it would be less potent in preventing MSDs if employees do not report injuries to their employers. Effective and open communication between employee and supervisor is vital to any work-related hazard prevention as this is the first step towards identifying and preventing hazardous work situations.

Occupational Health and Safety Regulation (OSHA) of Canada has defined new requirements in preventing MSDs under Ergonomics for the Prevention of Musculoskeletal Disorders. Many employers have access to ergonomic inspectors who can suggest ways to reduce risk of injuries. Local safety groups and Unions can provide more insight into available resources and prevention and rehabilitation programs.

Personal protective equipment and safety training are crucial for prevention of laboratory injuries. Just as important is knowledge of ergonomic principles to prevent MSDs. MSDs can develop into chronic disorder if left unchecked and can cause life-long problems and discomforts; therefore, early intervention can be useful and essential in preventing progression of MSDs, and the resulting economic impacts to the employee and the employer. Knowledge of ergonomics, improved pipetting techniques, and use of ergonomic pipets can help reduce the risk, and can even prevent, muscular strain injuries.

Equip yourself with knowledge of task, recognize the capacity of your body, and prevent injuries.

References:

1.Erickson, J. & Woodard, B. *Smart Pipetting: Using Ergonomics to Prevent Injury.*

2.McGee, R., & Bevan, S. et al. (May 2009). *Fit for Work? Musculoskeletal Disorders and the Canadian Labour Market.* London: The Work Foundation.

3.VistaLab Technologies. (n.d.). *Ergonomic Pipetting*. Retrieved from VistaLab Technologies:
http://www.vistalab.com/ergonomic.asp

CMPT would like to introduce two new members of its Clinical Microbiology experts Committee

Ms. Lorraine Campbell from Calgary Laboratory Services, Calgary, AB has joined CMPT's Clinical Microbiology expert committee.

Ms. Campbell has more than 15 years of experience in the Clinical Microbiology laboratory.

We are excited to have her on our team and thank her for her dedication and support.

Welcome Lorraine!

CMPT also welcomes **Ms. Brandi Keller** from Battleford's Union Hospital, North Battleford, SK as a member of the Clinical Microbiology committee.

Ms. Keller has extensive experience in Clinical Microbiology and Quality.

We look forward to working with her and thank her for the time and contribution to the team.

Welcome Brandi!

Carbapenem-Resistant Enterobacteriaceae screen

CMPT has completed the preliminary testing of the use of simulated rectal swabs as a quality measurement tool. These swabs can be used to assess the ability of laboratories to detect the presence of carbapenem-resistant *Enterobacteriaceae* (CRE) by screening rectal swabs.

Two surveys were sent to CMPT Clinical Microbiology participants in November 2014 and May 2015.

Results of these surveys are very promising, indicating that the participants are able to detect these organisms even at low concentrations.

CMPT is evaluating the possibility of creating a new PT program for those laboratories interested in assessing their ability to screen CRE in rectal swabs.

Please stay tuned for more information on this program or contact CMPT if you are interested in participating.

Check the reports for both surveys: November 2014, May 2015

Dr. Michael Noble presents at the national level Continual Medical Education meeting - China

Dr. Michael Noble was invited to give a presentation at the national level Continual Medical Education (CME) meeting in Jingmen, Hubei Province, China. The meeting was hosted by the Quality Control Center of Laboratory Medicine of Jingmen.

Dr. Michael Noble presents at the CME program 2015 in Jingmen, China

Dr. Noble was invited by the head of the Quality Control Center of Laboratory Medicine in Jingmen, Dr. Pei Wang, who visited CMPT for two months in 2014.

Dr. Noble's presentation focused on the quality control of MALDI-TOF MS; the lecture was part of a focus group on rapid detection techniques and rapid result reporting in clinical microbiology.

The CME program is a good opportunity for Chinese participants to learn advanced concepts and new notions in clinical microbiology.

It is a common tradition for the host country to invite international experts to give a lecture for their own audience. Dr. Pei explained that he hopes to cooperate and share some ideas with CMPT in the future.

CMPT's Professional Development Course

As announced in the Spring issue of Connections, a Professional Development Opportunity is coming this fall to CMPT participants' laboratory staff. After a brief pilot run to test the site, the CMPT Professional Development Course will officially start on October 2015.

This is an opportunity available to staff of laboratories enrolled in any of the CMPT proficiency testing programs and is free of charge.

The CMPT Professional Development course is a year-long course comprised of three different categories: Clinical Bacteriology, Mycology, and Enteric Parasitology. Each category has 3 to 4 modules.

The requirements for the course are: registering for the course, reading the challenge critiques for each category, and completing an online assessment or Quiz for each module.

CSMLS Assessment

	PEP Hours	CPS Credits
All modules	24	1.6
All Clinical Bacteriology modules	15	1
All Mycology modules	4.5	0.3
All Enteric Parasitology Modules	4.5	0.3

Earlier this year CMPT submitted the CMPT Professional Development Course to be evaluated for Canadian Society for Medical Laboratory Science (CSMLS) PEP hours or Credits.

CMPT has taken this initiative in response to requests from laboratory directors who understand the benefits that reading CMPT challenge critiques would bring to laboratory staff.

CMPT is pleased to announce that the course has been assigned PEP (Professional Enhancement Program) hours and CPS (Continual Professional Studies) Credits.

Each time a participant completes a quiz she/he will receive an email confirming the result of the quiz and the points obtained. An official certificate will be issued at the end of the course year to each participant completing all modules of a category so that PEP hours and/or CPS Credits can be claimed.

We are pleased to have 40 participants already registered for the site! The current quizzes available at the site will be active until the end of August for those willing to try them.

An email will be sent to announce the official start of the course closer to the date.

Please email Veronica Restelli (restelli@mail.ubc.ca) if you have any comments or questions on the CMPT's Professional Development Course.

You can visit the course's website: http://pd.cmpt.ca/ and register at http://pd.cmpt.ca/?page_id=210

Upcoming Events

SEPTEMBER 2015

5th Proficiency Testing Conference

September (15)16 -18; Timisoara, Romania

More info: http://www.pt-conf.org/index.php

ICAAC/ICC 2015

September 17 – 21 2015; San Diego, CA

More info: http://www.icaac.org/

OCTOBER 2015

Laboratory Quality Management Conference

October 28 – 30 2015; Vancouver, BC

More info: http://polqm.ca/conference_2015/home.html

JUNE 2016

LABCON 2016

June 16 - 19, 2016 Charlottetown, Prince Edward Island

More info: http://labcon.csmls.org/en/

ABOUT CONNECTIONS

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