



Featured Contributor

Janette Wassung, Head of the Quality Division, PathCare

1. Currently, you are Head of the Quality Division at PathCare Pathology Laboratory group in Cape Town, South Africa. Can you please describe a bit about the work you do in this position?

PathCare is a group of private laboratories in Southern Africa with more than 60 laboratories and 120 phlebotomy centers across South Africa, Namibia, Nigeria, and Kenya. The role of the Quality Division is to ensure that the best possible quality results and services are delivered throughout our laboratories and collection centers. This is ensured through employment of competent staff, participation in external quality assurance programs, and accreditation to International Organization for Standardization (ISO) standards. As head of the department, it is my role to facilitate this level of quality.

The PathCare Quality Assurance Division is responsible amongst other things for the following:

- Quality control programs
- Internal audit program
- Compliance with accreditation and other regulatory bodies
- Method standardization and validation
- Maintenance of standard operating procedures (SOPs)
- Training in quality assurance

2. Tell me about your experience as a member of the Document Development Committee on Quality Management System: Laboratory Internal Audit Program (QMS15).

For me, being a member of QMS15 has been an opportunity to share knowledge of “how it’s done at PathCare” as well as learn from other countries and organizations. The interaction with other members and observers is probably the highlight of any CLSI meeting!

3. Describe your contributions to the CLSI Working Group on QMS: Inspections and Accreditation Assessments.

Members of this committee included many other accreditation bodies. Through the interactions of drafting this document, I have learned that there are many different ways to consider compliance to ISO 15189; there is not one set of rules. This is important to understand, and if you work with one accreditation body in a country, it opens up opportunities to engage with your country’s accreditation body, either to facilitate a positive change or to better understand

its processes. As a member of this working group, I was also in a position to share my knowledge on what we experience as a client of an accreditation system.

4. How have you benefited by becoming a CLSI volunteer?

Becoming a volunteer for CLSI has been one of the highlights of my life! It has opened so many doors and opportunities for me as an individual, as well as to PathCare as an organization. I have grown tremendously professionally through my interaction with CLSI. With the various South African links to organizations that I have, I was able to transfer knowledge to South Africa as a country. The CLSI journey has thus far been a truly amazing one!

5. What are some highlights or resolved consensus issues in the CLSI document development process of which you are particularly proud?

The writing of QMS15 was particularly difficult at first, because the document is aimed at both the audit program and the audit process. Concepts of these two systems overlap and created some confusion for the working group, which delayed the timeline for this document. When we managed to get the flow of the document right and differentiated between the audit program and process, all fell into place and we were able to complete the document at a much faster pace.

The new format and layout of the CLSI documents is so much better! Much more user-friendly, lots of color with a good flow—a wow factor indeed!

6. Do you believe CLSI documents are helpful resources for professionals in your field in day-to-day practice?

Oh absolutely, without a doubt! Through CLSI membership, PathCare has been able to convert many of our processes and SOPs to CLSI guidelines; and while there are many other similar organizations that offer guidance, I have found the CLSI documents to be the most comprehensive. PathCare is in a position to compare ourselves favorably with other international laboratories, as CLSI has become the norm in many laboratories.

7. What do you see as the most pertinent issues right now in your field?

Point-of-care testing! There is still a lot of work that needs to be done on point-of-care testing (POCT). There are so many challenges, near-patient testing versus POCT. The scope where POCT is used is vast and is often done uncontrolled.

8. You are currently working in South Africa. How does your field differ in the United States and other countries?

In South Africa, about half the laboratories are public and half the laboratories are private. Most of the private laboratories are accredited through the South African National Accreditation System according to ISO 15189. We do not use CAP, A2LA CMS, etc. ISO has also become the standard to which laboratories aspire in Africa, with PathCare being the first laboratory to be accredited to ISO standards in South Africa, Nigeria, and Kenya. The African Society of Laboratory Medicine is now following a path of a tiered momentum towards quality standards being introduced in Africa according to the WHO structure for accreditation (SLIPTA - Stepwise Laboratory Quality Improvement Process Towards Accreditation).

The health care environment in South Africa is different from many other parts of the world in that there are distinct differences between the public and private sector, both in terms of funding and quality of outcomes, leading to much debate related to how to best improve standards for all in South Africa.

9. If you had never gotten into the health care arena, what would you be doing for a living?

I always had a passion for a career in the financial sector.

10. What has been the highlight of your professional life?

Oh, I think this is the opportunities that presented themselves for me to be involved in international arenas such as CLSI and ISO. Also, the fact that I was able to have an influence to create space for South Africa to be represented at ISO/TC 212, through the South African Bureau of Standards.

11. What has been the highlight of your personal life?

This has to be the opportunity to see a live concert of Neil Diamond in South Africa a few years ago with my husband. WOW, what a highlight that was!

12. What is an interesting fact about you that most people would not know?

I talk so much that I almost cannot imagine there is anything people don't know about me. Probably the fact that I "used to be" able to sing! I sang in school and church choirs quite a bit "in my previous life."

13. What is your favorite hobby?

My favorite hobby is spending time with my two cats, Bacardi and Whiskey!