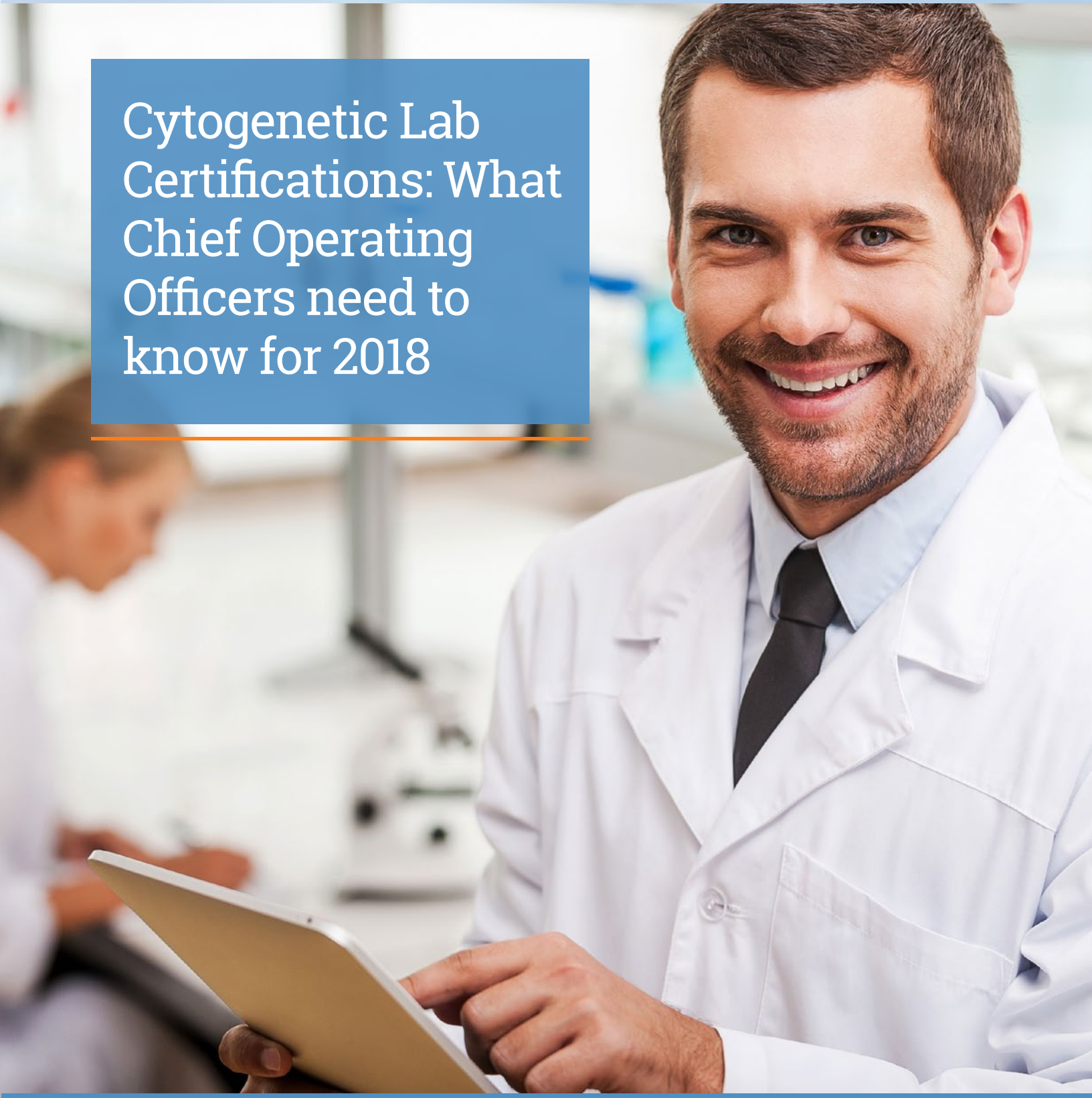
Virtual Scientific

quality, accuracy, efficiency

Cytogenetic Lab Certifications: What Chief Operating Officers need to know for 2018



As advances in the testing of cytogenetic specimen increase in complexity, it becomes more important for laboratory testing facilities not only to become credentialed but also to understand the landscape of credentials in today's marketplace. As the industry leader in turnaround time (TAT), **Virtual Scientific** understands how important it is to staff our labs with the most qualified, fully credentialed technologists in the field. There are four primary testing credentials for the field of cytogenetics and within those, several board certifications that lab managers may undertake according to their specialty. The primary objective of the various cytogenetic lab certifications is to ensure accuracy, reliability, and efficiency of lab testing results.

Virtual Scientific **recently noted** that there is currently a great shortage of qualified technologists in cytogenetics, an industry which is expected to have grown by 13 percent between 2010 and 2020. For that reason, many lab technologists will no doubt seek the training and credentials necessary to become a certified cytogenetic technologist. That's why we are taking this opportunity to look ahead to some of the items related to credentialing that you'll need to know for 2018.

Clinical Laboratory Improvement Amendments (CLIA) Certification

Even though it has been in place since 1988, the CLIA Certification remains one of the most important credentials in the laboratory testing space. Over the past 30 years, the original CLIA regulations established in an amendment to the Public Health Service Act of 1988 have acquired more than 130 amendments to bring its statutes in line with current technologies and to reflect best practices around laboratory testing.

Implementation of CLIA certification standards is overseen by the Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ). This body, along with all cytogenetic laboratory testing, is regulated by the Centers for Medicare and Medicaid Services (CMS). In all, according to CMS, CLIA standards ensure quality testing at approximately 254,000 laboratory entities in the United States.

To achieve CLIA certification, you will have to fill out the CMS-116 application and submit it to your state CMS agency. Once processed, your testing facility will receive an invoice for a one-time fee. When that fee is paid in full, CMS will mail the CLIA certificate. Some states require additional state licensure for clinical laboratories. Arizona, on the other hand, requires only that laboratories carry CLIA certification. Make sure to familiarize yourself with the regulations governing laboratory operation in your region.

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA, which Congress enacted in 1996 as an incremental healthcare reform measure, has evolved through multiple revisions to focus largely on protecting patient privacy. According to HIPAA regulations, HIPAA compliance is required for "any organization or person who works in or with the healthcare industry or who has access to protected health information." This includes all healthcare providers, health insurance companies, healthcare clearinghouses, and employer group health plans. All laboratory testing facilities in the United States fall under the jurisdiction of HIPAA regulations.

In order to achieve HIPAA certification, individuals and organizations must undergo HIPAA training. Organizations, including laboratory testing facilities, must distinguish between HIPAA's two areas of designation in their training, either HIPAA Privacy or HIPAA Security. All groups, according to HIPAA training guidelines, must comply with the HIPAA Privacy regulations. Only those entities that store and protect electronic patient data need to comply with HIPAA Security regulations.

Attaining HIPAA certification is a three-stage process:

- Provide HIPAA Awareness Training to all employees who have access to Protected Health Information (PHI)
- Implement formal documents and controls to protect PHI
- Train an employee of your organization to act as a HIPAA compliance officer

Once compliance has been achieved and you have been issued your certificate of completion, your HIPAA certification is valid for a two-year period. Some organizations will require yearly retraining based on their individual recertification policy.

Good Clinical Laboratory Practices (GCLP)

The emergence of Good Clinical Laboratory Practices (GCLP) coincided with the merging of Good Laboratory Practices (GLP) with Good Clinical Practices (GCP) into a single set of regulatory standards designed to bring greater accuracy and accountability to the rapidly growing sphere of medical testing facilities. GCLP is unique in that it borrows QC elements from GLP and ethical elements and scientific standards from GCP. According to the Global Health Network, the combined standard "ensures the quality and reliability of the clinical trial data generated by laboratories."

GCLP standards touch on all areas of clinical laboratory operations, including standard operating procedures, equipment and materials handling, work flow planning, subcontracting, quality control and quality audits, records storage, confidentiality, personnel and facilities management, as well as some additional aspects of the laboratory environment. Implementation of GCLP standards is overseen by the Department of Health and Human Services (DHS) with supplemental documentation provided by the Food and Drug Administration (FDA). Due, however, to certain ambiguities in the text of the GCLP regulations related to intent, other accrediting agencies, such as the International Organization for Standardization (ISO) or the College of American Pathologists (CAP) may provide guidance on a range of issues.

In 2011, a coalition of government agencies including the National Institute of Allergy and Infectious Diseases, US National Institutes of Health created the 'Division of Acquired Immunodeficiency Syndrome (DAIDS) Guidelines for Good Clinical Laboratory Practice Standards,' which apply to testing facilities participating in DAIDS-funded clinical trials.

The GCLP standards certification process requires both lab personnel to receive specialized training and for their lab to receive a strategic assessment, assuring regulators of the quality, reliability, and integrity of results produced.

American Society for Clinical Pathology (ASCP) Board of Certification

The top cytogenetics testing labs will generally hire only ASCP certified technologists. ASCP certification is the top standard for medical lab professionals. Since its founding in 1928, the ASCP Board of Certification has granted the designation to more than 525,000 individuals.

To become board certified, a medical technologist must undergo an initial eligibility assessment using ASCP's user-friendly online tool. Once eligibility is established, candidates for board certification must take the exam which corresponds to their area of specialization. There are 21 disciplines—each having their own exam—that are eligible for certification, including Medical Laboratory Scientist (MLS), and Cytogenetics (CG).

Thanks to this brief overview of the primary certifications available to technologists in the field of cytogenetics, you should now be able to explore these themes in greater depth and determine how you might begin your own credentialing process.

Outsourcing your cytogenetic testing is also a very common industry practice. Virtual Scientific can save your business valuable time and money by conducting your cytogenetic testing needs. Our laboratories and technologists have all the certifications and accreditations mentioned in the article above, so that your work flow can stay intact, no matter the testing application. Virtual Scientific clients benefit from our industry-leading TAT, and our highly experienced ASCP certified technologists integrate into your team seamlessly, adapting easily to different analysis protocols.

Contact Virtual Scientific today to learn more, or take our free assessment to learn how you can grow your testing capacity and improve your bottom line by partnering with us.