

Companion Diagnostic Care

WHO ARE THEY? ¹

A career in companion and clinical diagnostics development, within the pharmaceutical industry means that these professionals are the ones looking at the big picture of patient care. Their job is to ensure that the medical devices that they create supply critical information that is essential for the safe and effective use of a corresponding drug or biological product. The role includes aspects of both clinical research and business management. These professionals are meticulous, thrive in teams or labs, and are comfortable making important, independent decisions in an environment that can change rapidly. Professionals in companion and clinical diagnostic development are important because the work they do in creating devices for precision medical care is incredibly complex, often spans the globe, and the safety and well-being of the patient is at stake. Precision medicine, sometimes known as “personalized medicine” is an innovative approach to tailoring disease prevention and treatment that incorporates differences in people’s genes, environments, and lifestyles.¹ The goal of precision medicine is to target the right treatments to the right patients at the right time. If you are interested in the field of biotechnology and public health but would prefer to work the area of personalized medicine, a career in companion and clinical diagnostics development might be a great fit for you.

WHAT DO THEY DO?

In the last few years, more drugs are being designed for smaller, more specialized populations of patients. The companion and clinical diagnostic development scientist is charged with addressing the important and unique issues for diagnostics used in this kind of personalized medicine. These might include policy and process-related issues, helping to coordinate regulatory oversight between centers globally, and ensuring efficient review of personalized medicine products and devices across the full product life cycle. These leaders often manage the entire research process to provide critical technical knowledge, collaborate closely with other leaders in sample operations, clinical operations, and with regulatory representatives.

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SALARY RANGE

\$65,000–\$100,000

EDUCATION/TRAINING

Ph. D. (preferred) in a Life Science or equivalent (M.S. or B.A. with equivalent relevant experience is acceptable)

3–5 years of relevant work experience

Broad knowledge and understanding of new and proven clinical and diagnostic assay technologies

Hands-on experience with diagnostic assay development and data analysis is strongly preferred

Experience in the drug development process (clinical trials, efficacy endpoints, biomarker testing)

Strong understanding of the decision-making process in the biotech/pharma industry

Must be detail-oriented with strong project management and organizational skills

They might prepare protocols for the trial, decide monitoring and data management procedures, develop recruitment methods, secure needed materials for clinical trials, and coordinate the whole trial to ensure it runs smoothly. This person may also train other staff who will play key roles in the trials. A career in companion and clinical diagnostic development requires advanced organizational strategies, excellent people skills, and strong attention to detail.

JOB OUTLOOK ²

The Bureau of Labor Statistics notes that the whole field of pharmaceutical development, which includes companion and clinical diagnostic development, is projected to grow rapidly over the next 10 years. Precision medicine is using companion devices that are developed right alongside the full product life cycle of therapeutic drugs and medicines. They are used across the world on any given day. These professionals are in high demand because of this. They may have the chance to work in hospitals, for pharmaceutical companies, for clinical research organizations, or even in government positions. Because there are many levels of position in this field—from coordinator to director level—this is a career path that allows one to grow within the career.

HOW DO I BECOME ONE?

A unique aspect of companion and clinical diagnostic development is that candidates often begin in other roles, such as lab associate, lead technician, or researcher in other areas of the medical field. They are likely to have a Ph. D or at least a MS degree in a biological or biomedical science, or in biotechnology. They often have experience as research associates and leaders. They may have certifications from organizations like the Association of Clinical Research Professionals or the Society of Clinical Research Associates. They may have other professional certifications. A student interested in this industry can choose laboratory science coursework starting in high school and should concentrate on building critical-thinking and analytical skills in other courses such as Biology, Genetics, or Computational Thinking.

1 *LRx Precision Health*, <https://lrprecisionhealth.com/about-us>.

2 The Bureau of Labor Statistics. <https://www.bls.gov/>.