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Preface

As hiring managers, my colleagues and I have always struggled to fill open clinical positions, despite an abundance of applications. We sift through mounds of résumés from eager and talented applicants, including many from the research laboratories of our own companies. Unfortunately, we reluctantly reject most of those applicants, because they lack one important prerequisite: clinical experience. Even for entry level positions, for which such experience is not absolutely required, we prefer to hire people who have an understanding of clinical studies. Those who don't are at a significant disadvantage.

Clinical experience is not just another item in the job posting for drug, medical device, and contract research organization (CRO) companies. These companies are obligated by regulatory requirements to employ only clinical workers who are qualified for the jobs they hold and to ensure that they update those qualifications through internal training programs. For new employees who lack clinical experience, the company (and more specifically, the hiring manager) must invest considerable resources in clinical training before the workers can be assigned official responsibilities on clinical studies.

Clearly, physicians, nurses, and pharmacists have acquired relevant experience and easily meet this job prerequisite. However, most of the positions in industrial clinical departments, particularly at the entry levels, do not require a medical degree or healthcare licensure. What is particularly frustrating to us, as hiring managers, is that undergraduate and graduate students can acquire, in a number of ways, clinical experience that we will accept, and it is not difficult to obtain. If only someone would explain to job seekers how important clinical experience is and provide information on how to obtain it.

A second frustration for hiring managers is that many talented and potentially interested candidates are simply unaware of the job opportunities in industrial clinical departments. Academia generally does not

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inform or prepare students for careers in research and development of new medical products. It is simply amazing to me that so many of my industry coworkers stumbled upon their careers in clinical research, like I did, merely by chance. In most cases, once those opportunities were presented to us, we found fulfilling and successful careers. Undoubtedly, other eager job seekers would also find this career path attractive. If only someone would tell them about it.

For those with an interest in science and a desire to find better treatments for patients, this book will pull back the curtain on rewarding and lucrative career opportunities that are rarely mentioned in academic degree programs. For those who were lucky enough to discover clinical jobs in industry, this book will explain strategies for landing an entry level job as an outsider—including, specifically, how to get that all-important clinical experience.

The book covers clinical research that is conducted at pharmaceutical, biotechnology, medical device, and CRO companies. At various times in my career, I have had the privilege of working in the research and development divisions of all of those industry segments. However, I am indebted to a number of coworkers and professional colleagues who assisted me in various capacities and without whom this book would not have been possible.

First and foremost, I am deeply grateful to Susan Aiello and Diana Patten, who freely offered their insight, guidance, and encouragement throughout the entire course of this project, from development of the original concept to completion of the book. I am equally grateful to Julie Silver and the faculty of her non-fiction book course at Harvard's Department of Continuing Education. The course provided invaluable advice on all aspects of non-fiction writing and book production, and it inspired me to push my writing ambitions to levels I had not previously considered.

The following individuals graciously provided input and perspective on various topics covered in the book and verified specific factual information: Kathleen Block, Laura Bloss, Patti Brennan, David Mee, Angela Meisterling, Betty Mendes, Diana Quinto, Peggy Smith, John Tiso, David Townson, and Kristina Welch.

I am also grateful to the following subject area experts who carefully critiqued the chapters related to their professional expertise, provided many helpful suggestions, and verified the content: Frances Akelewicz, Shelia M. Brown-Walker, John Constant, Ann Dugan, Marta Fields,

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MaryAnn Foote, Nicole Harasym, Sue Hudson, Donna Jacobs, Susan Lyman, Carol Marimpietri, Patricia Mighetto, Mary Bernadette Ott, Heidi Reidies, Rob Tarney, and James Yuen.

Finally, I owe a special thanks to my Developmental Editor, Judy Cuddihy, who has patiently guided me through the editorial process, offered many helpful suggestions for improving the book's content, and explained the finer points of book publishing. Due to her efforts, the book is much better than it otherwise would have been. I also thank the staff at Cold Spring Harbor Laboratory Press, including Publisher John Inglis, Project Manager Mary Cozza, Production Editor Mala Mazzullo, Director of Development, Marketing, and Sales Jan Argentine, and Production Manager Denise Weiss for their support and exceptional efforts in producing the book.

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1

What Is the Clinical Environment in Industry?

WANT A JOB THAT PAYS WELL, has excellent benefits, and offers fast-track promotions? Want to work for an employer who provides a pleasant work environment with state-of-the-art equipment, encourages on-the-job training, and pays your travel expenses? And on top of that, how about a job aimed at improving patients' health and sometimes saving their lives? If you want to go home every night with a warm feeling inside—and get paid for it—then this book is for you. Working on clinical studies gives you all these perks and offers you a satisfying and rewarding career.

Before any new drug can be marketed, it must undergo extensive clinical testing (i.e., studies using patients) to demonstrate that it is safe and that it has therapeutic value. The makers of medical devices must also conduct studies in patients to evaluate the safety and performance of products such as pacemakers, heart valves, and artificial hips.

Lots of people work together to conduct a clinical study, and most of them are not physicians. You can qualify for many jobs in clinical fields, such as clinical operations, data management, quality assurance, and regulatory affairs, with just a bachelor's or graduate degree. But there's a catch. To qualify for most clinical research jobs in the medical products industry, you need to have prior clinical experience; hiring managers won't even consider you without it. So, how do you get started?

This book will show you how to qualify for those jobs and launch a lucrative, rewarding clinical career developing new drugs or medical devices. Part I explains how drug and medical device companies conduct clinical studies, with an emphasis on the jobs that are easiest for you to enter as an outsider. In Part II, you will learn what people in each of those entry-level positions do, what qualifications you need, and most importantly how to get "clinically relevant" experience that a hiring manager

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will accept. Part III gives you practical advice for conducting a successful job search and landing your first clinical job.

As you will quickly see, the world of clinical studies has its own terminology. Each chapter explains technical terms as they are introduced. In addition, a glossary is included for your reference. (Building your vocabulary of clinical study terms will give you another advantage during your job search. After all, hiring managers expect you to have a basic understanding of the terms they use every day.)

WHERE ARE THE JOBS?

The companies that are required by regulatory agencies to conduct clinical studies fall into three categories: pharmaceutical, biotechnology, and medical device companies. Pharmaceutical companies (sometimes called big pharma companies) are mostly large, multinational companies. The drugs that they manufacture and sell are organic chemicals, which they either synthesize by chemical reactions in the laboratory or extract from natural sources such as plants. Biotechnology companies (or biotechs) make and sell drugs that are manufactured using molecular biology and genetic engineering methods. Scientists create biotech drugs by modifying biological substances (such as proteins or antibodies) from their natural form and manufacture the product using biological fermentation methods.

Many companies now develop both biotech and chemically synthesized drugs, thus blurring the distinction between pharmaceuticals and biotechnology. Biopharmaceutical (or biopharma) is a collective term that refers to both biotechnology and pharmaceutical companies and the drugs they produce. Most biopharmaceutical companies have their headquarters or a major branch office in the United States, which is where most of the opportunities for clinical development jobs are located.

Medical device companies make and sell nondrug products for patient use, ranging from home pregnancy tests to treadmills to heart-lung machines. Of these, Class I and II devices are those whose failure or misuse have little or no impact on patient care, are unlikely to cause direct patient injury, and therefore generally are not tested in clinical studies. On the other hand, Class III medical devices, whose failure or misuse is reasonably likely to cause serious patient injury (such as fetal monitors, silicone breast implants, and asthma inhalers), require clinical testing similar to that conducted by drug companies. Most medical device

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companies are small, entrepreneurial companies and develop one, or only a few, products. A few, large medical device companies develop and sell a wide range of products for hospital or home use.

Biopharmaceutical and medical device companies sometimes need additional workers to carry out their scheduled clinical studies. Rather than hire additional staff to meet short-term or specialized needs, they typically turn to contract research organizations (CROs). As the name implies, CROs lend the services of their trained employees to client companies; they do not develop their own medical products. Because the medical products industry is highly regulated, CRO employees must have the same qualifications and be able to conduct clinical studies with the same standards as their clients. CROs range in size from small, specialty contractors to large, full-service companies. Most of the large, multinational CROs have their headquarters or a major affiliated office in the United States, which is where most of the opportunities for clinical jobs are located.

Biopharmaceutical, medical device, and CRO companies always need workers to conduct clinical studies. Once a study starts, a drug or medical device company is committed to follow through until the study's completion, and many clinical studies continue for more than a year. When biopharmaceutical and medical device companies are thriving and growing, they expand their clinical departments to support development of their new products. When those companies are struggling financially, they will cut back their budgets and perhaps lay off staff. However, they must continue to support their ongoing and planned clinical studies. When internal resources are limited, they engage CROs to conduct or continue the studies on their behalf. CROs thrive and grow to accommodate increased requests for their services, sometimes with remarkable growth of their workforce.

Thus, despite wide fluctuations in the economy and other factors, openings for clinical jobs in medical product development are always available. Sometimes, most jobs will be at biopharmaceutical and medical device companies; at other times, the jobs will be at CROs. But there will be jobs.

INDUSTRY CLIMATE

The Research and Development (R&D) division of biopharmaceutical and medical device companies encompasses three separate work cultures.

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Each is driven by the nature of the work, which differs in its goals and the methods used to achieve them.

Research scientists and engineers who work in industry laboratories are charged with finding novel and innovative products to treat or diagnose disease. Their research activities are not very different from academic or independent research laboratories, except that they are expected to work toward the goal of discovering a therapeutically useful product. They are encouraged to be creative, explore the latest frontiers of science, and take risks. Except for rules that protect the environment and their own safety, their work is not constrained by regulatory requirements or company-imposed standard procedures.

A second group of laboratory scientists and engineers is charged with taking a discovery made by the research scientists and assessing its potential as a commercial product. This preclinical assessment is the first stage of a new product's development. These development scientists and engineers collect a well-defined set of data that describe the product's characteristics and performance in a controlled laboratory setting, including tests in animals. The work environment is much more structured than research laboratories, and workers follow regulatory requirements for Good Laboratory Practices (GLPs), which not only stipulate the required design features of the experiments but also the rules for recordkeeping, equipment calibrations, and controlling experimental variables.

The third segment, and by far the largest, longest, and most labor-intensive aspect of R&D, is the work of the clinical department. Healthcare professionals and many other skilled people work in teams to take products that survive preclinical assessment and determine their therapeutic value in patients. Like the preclinical development environment, the clinical culture is highly structured, and workers follow regulatory requirements for Good Clinical Practices (GCPs), which ensure the safety and welfare of patients during treatment with experimental products, as well as the integrity of the data.

Admittedly, working in an industrial clinical research setting is not for everyone. But for those who are comfortable in this environment, clinical work is personally and professionally rewarding and has many attractive features compared with academic and independent research laboratories. You can expect a collaborative work environment, a supportive but demanding senior management structure, lots of up-side career potential, and great fringe benefits.

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BOX 1-1. *Summary of Industry Clinical Climate*

- Good salary, bonuses, and benefits
- Generous study budgets
- More job security for clinical jobs than nonclinical area of R&D
- Coworkers are bright, hardworking, considerate, and talented
- First to see patients benefit from a new treatment
- Have a stake in new treatments that benefits millions of patients
- Resources available to do the job right
- Fast paced work
- Tight deadlines
- Long hours
- Innovation is encouraged but must apply to product development
- Able to present data in top-tier medical journals and at international conferences
- Scientific publication dates are coordinated with business needs and timetables
- Career advancement is based on performance
- Bureaucratic hierarchy
- Decisions are business-based, as well as science-based
- Highly structured and regulated environment
- Flexible, broad-based knowledge is more highly valued than narrow, deep expertise
- Frequent meetings and communication-intensive
- Direct contact with patients is limited
- Reorganizations are common

Collaborative Environment

Clinical studies are a lot like ice hockey. They require a team effort, each person playing a defined position and supporting his or her teammates, to reach the goal. The clock is always ticking. The team must overcome many barriers, sometimes by brute force, to make forward progress. Team members are often sidelined or substituted at critical points along the way. Success is not assured, even when the team does its best. When the clock runs out, the team heads for the showers—perhaps battered and

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bruised—either to pop the champagne corks or simply to think about the next game.

Yes, it's a rough-and-tumble process. Managing an experimental product through a battery of clinical studies is long and complicated. The work is fast-paced, the competition between companies is keen, the deadlines are tight, and the pressure is constant.

Nevertheless, clinical departments operate in a friendly, informal atmosphere and are generally very pleasant places to work. Clinical investigation of new therapeutic modalities creates a culture founded on highly intellectual research and scientific innovation—the application of cutting-edge science to address human health needs. Everyone is bright, hardworking, considerate, and talented. Employees earn the respect and cooperation of their coworkers, subordinates, and supervisors through their knowledge and helpfulness, not by touting their academic credentials. Clinical teams are motivated to work long hours by the satisfaction of doing something that is truly worthwhile—improving healthcare with new and better treatments.

Everyone in a clinical department shares in a real sense of accomplishment, no matter how small their individual contributions might be. They are the first to see the impact of a new treatment on a patient's medical condition, which may have been previously untreatable. They may see their work presented in medical journals and at world-class medical conferences. Better still, they may rightfully claim a direct contribution to the successful launch of a new commercial product that improves the health of millions of people.

Clinical teams are given a wealth of resources to "do the job right." To supplement the knowledge of their talented colleagues, they regularly invite key opinion leaders from academia and private research institutes to serve on advisory boards or as consultants. Cutting-edge science means that there is no existing blueprint for designing appropriate clinical studies. Clinical teams, therefore, seek advice from the best and brightest medical experts, some of whom may also participate in the studies as clinical investigators. These interactions with external consultants are mutually beneficial: Clinical workers develop a personal rapport with highly regarded medical experts and those experts may gain early access to new treatment modalities for their patients.

In addition, clinical workers can draw on an extensive internal infrastructure to assist them. Librarians and information specialists routinely monitor and alert clinical workers to newly published research findings

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and the status of competitors' products. Other information technology specialists install and maintain computer software and hardware. Contract and patent attorneys handle the legal aspects of negotiating agreements for external services and protecting the company's intellectual property. Finally, R&D divisions prepare an annual clinical budget to cover the cost of planned clinical studies, including the costs of clerical staff, facilities, and equipment. Finance and accounting experts track clinical study expenses and prepare financial reports. Aside from the annual budget discussions to share their clinical study plans for the coming year, clinical employees usually do not worry about finding funds for their work, unlike their counterparts in academia.

Each clinical study is different, presents its own challenges, and never fails to produce a few surprises no matter how carefully the team has planned it. To keep the product's development on track, clinical teams face a wide range of problems, large and small, some stimulating, and some frustrating. Certainly, there's never a dull moment and the job is never boring.

Developing a new drug or medical device also has a high failure rate. Sometimes, the product fails because of an inherent, insurmountable flaw, even though every team member did everything right. Clinical workers must cherish their successful days amid months of disappointment and distinguish between their personal performance and the product's (sometimes flawed) characteristics. Accepting many disappointments is the price all scientists are willing to pay to savor those few, experimental breakthroughs. Clinical workers in industry must be willing to move on to other projects for business as well as scientific reasons.

Clinical workers are encouraged to be innovative, but their creativity must be channeled along narrow paths. Innovative processes or procedures that save time and money are always valued and rewarded. Sometimes, data collection to answer exploratory questions can be incorporated into the design of essential clinical studies without detracting from the product's development timetable. Such data sometimes can serve as the starting point for a new clinical program, and teams are encouraged to pursue those leads. However, the opportunities to explore open-ended scientific questions are limited.

Clinicians are encouraged to be attentive to unexpected results from their planned studies and to explore the implications of those results. Some of the most successful drugs, such as Viagra®, have come from unanticipated results of clinical studies that were pursuing a different

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therapeutic use. However, such exploratory work must be conducted with a commercial opportunity in mind, not simply for its value as an intellectual exercise.

Some clinical studies, frankly, are not innovative and only serve to satisfy a regulatory requirement or business need. Examples include comparing an existing drug formulation with a new, improved formulation; determining the proper dose level for various patient groups (such as children vs. the elderly); and testing a product's ease of use (such as two models of blood glucose monitoring kits). However, even in these cases, attentive and bright investigators may uncover a new medical condition (such as patients with a genetic anomaly) or develop innovative computer models to interpret their results.

Decision making is structured in clinical departments. Individuals and teams are empowered to determine the course of their daily work, but senior managers make decisions that have a significant financial impact. Decisions to choose between several alternative experimental lines may fall either to the clinical workers, the senior managers, or both. Although individual input on scientific questions is solicited from all of the internal experts who have a stake in the topic, decisions are made for the good of the company and the best path for developing the product, rather than an individual's preference for pursuing a personally interesting sidelight. The decision making process is not always democratic, and the company's senior managers have the final word.

Clinical departments organize their work in a hierarchy of cross-functional teams. Clinical study teams carry out individual clinical studies. Strategy or project teams coordinate groups of clinical studies needed to develop a single product. Senior management teams oversee, coordinate, and control development of all the products in the company's portfolio.

To oversee and manage the work at all levels and between levels requires extensive, ongoing communication. Large companies are more bureaucratic than small companies, but in all cases, clinical departments have a culture that generates many meetings and incorporates many different viewpoints before making a decision and taking action. Things are less spontaneous than in academia or independent research companies, and clinical workers spend a lot of time in meetings and generate a lot of e-mails, memos, and reports.

However, the structure, hierarchy, and management oversight also provide more career opportunities and options than those available in academia and independent research laboratories. Pay raises, bonuses, and

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career advancement are based on performance, and performance is judged not so much by what employees achieve individually, but rather by how much they contribute to the success of the teams and projects on which they serve. Industrial employers, therefore, are conscientious about conducting annual performance reviews.

Performance reviews not only document past performance; they also serve as the basis for discussions regarding the employee's future work, and supervisors are expected to assist the people who report to them with their career development. Based on these discussions, workers are encouraged to set job-related and career-enrichment goals for the coming year and plan supplemental training or other activities to strengthen their skills. Through individual coaching, which may be ongoing, supervisors also help employees qualify for promotion or their next career goal.

With regard to career advancement, clinical workers have an advantage over those who work in other areas of R&D. In medical products companies, clinical studies are the most visible aspect of R&D and garner significant attention from influential people in the company. Those who support clinical studies also enjoy greater visibility, and if they make significant contributions, their efforts are more likely to be rewarded, including rapid promotions and other opportunities for high-profile advancement.

Clinical departments put great effort into grooming leaders and managers: People who can inspire others to channel their energy along productive lines. Most companies provide training programs to help clinical workers develop management skills. Those who are willing to take management responsibilities in conjunction with applying their technical expertise are most likely to move to highly responsible and influential positions in industrial clinical departments.

These promotions and high-profile assignments usually move employees further away from day-to-day involvement with clinical studies. Senior managers still assess clinical study results, but they have a broad, strategic vision and responsibility. Rather than concentrating on just one product, study, or clinical skill, they influence the direction of entire clinical programs through their decision making authority.

It's a Business

Companies that develop drugs and medical devices are heavily regulated to protect patients from unnecessary harm and to guide healthcare

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professionals to use those products correctly. The rules and regulations in clinical departments are extensive and set the boundaries for all of the clinical studies conducted during development of a new medical product. Consequently, there is a disciplined, businesslike aspect to the culture of clinical departments, dictated by the need to plan, authorize, and document each clinical activity.

Ironically, regulatory agencies permit almost no direct contact with patients while a company is developing a new medical product. This ensures patient confidentiality but it prevents company clinical workers from directly observing the product's effects during the study. They must rely on the data they receive from clinical investigators who treat, observe, and assess the study patients at remote clinical sites. (See Chapter 3 for details on investigator and clinical site activities.)

The absence of patient contact allows clinical workers to conduct their businesslike affairs in a relatively comfortable, casual setting. They interact with each other on a first-name basis, regardless of rank. The dress code is casual when they are working in the office or attending internal meetings. However, most companies expect standard business dress when clinical employees represent the company at external meetings or host visitors.

Workers in clinical departments generate a large volume of regulatory documentation. They must follow regulatory rules for collecting specific types of information, checking the content for accuracy, and archiving the documents for future reference. In addition, the company's patent attorneys require documentation to support patent claims and protect the company's intellectual property.

Because so much of the clinical work is conducted to satisfy regulatory requirements, those requirements largely determine the work that individuals and clinical teams must achieve. However, the company's senior managers usually set the deadlines for completing that work based on business needs, and the deadlines are always tight. Furthermore, senior managers may quickly change program priorities or work assignments based on business needs, unexpected study results, or both.

In well-run companies, the senior management's decisions are both business-based and science-based. Senior managers constantly assess which of their products will be the most profitable. If several development programs are competing for resources, managers will favor clinical studies and new product candidates that not only satisfy an unmet medical need but also enhance stockholder value.

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The same logic guides their decisions about publically disclosing data from clinical studies. They encourage company scientists and clinicians to publish papers in prestigious medical journals and present their work at high-profile meetings, because public recognition fosters the professional reputations of their employees, as well as the company's public image. However, they often impose constraints on the timing of publication. Release of the data may be authorized only after a development program or clinical study has been discontinued. Positive results may be delayed to coincide with a product launch or patent approval, or rushed to coincide with a stockholder meeting.

At CROs, the clients set the CRO workers' deadlines, which are always shorter than the deadlines imposed within the client company. The client company builds in time to review and, if necessary, ask for corrections of the CRO's work before its own deadline for completing the work. The client company also sets the requirements and scope of the CRO's contract services. Those CRO services may help the client company formulate its business strategy for product development, but the client's strategy is always determined internally. The CRO's senior managers, in turn, set work priorities to keep their most important clients satisfied. CRO managers may quickly change priorities or work assignments to accommodate a demanding client, the unexpected loss of contracted work, or the award of a major, new contract.

In short, the company's financial bottom line always comes first, be it a large pharmaceutical corporation, a small medical device company, or a CRO. The options for creative work schedules such as telecommuting, job sharing, and flextime are more constrained than those allowed by employers in academia or independent research companies. Any consideration for granting a flexible work schedule depends on the nature of the work and whether it serves a business, rather than a personal, need.

Similarly, industry employees can be "hired at will" rather than under a contract, and in this situation their job security is limited. However, because clinical study schedules are less prone to be impacted by changes in the company's balance sheet, clinical positions are generally more secure than those in manufacturing, sales, marketing, and the other divisions of R&D.

The business climate for drug and medical device companies has been volatile in recent years, and the interest in mergers and acquisitions will likely continue. When two or more companies merge, clinical departments are almost always reorganized, and sometimes programs and staff are consolidated.

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Decisions to lay off staff as a result of mergers and acquisitions follow a long and well-planned procedure of assessments, communications, and reorganization. In all but the smallest and most volatile companies, employees who are laid off are given a severance package of financial and outplacement assistance, proportional to their years of service.

Even without mergers, acquisitions, or layoffs, clinical departments periodically reorganize in an effort to improve efficiencies in work flow, processes, and procedures. Although job titles, reporting structures, and work units are often changed in these reorganization efforts, the regulatory-driven tasks carried out by clinical workers remain the same and are unaffected.

Whether the company's decision makers impose layoffs or reorganizations, employee flexibility is the key to survival in clinical departments. Workers who have expanded their résumés by acquiring a range of clinical study skills with different types of products in different therapeutic areas are more highly valued than those who have expertise and a deep knowledge of just one thing. Broad-based clinical study knowledge and experience can be leveraged to new opportunities within the company or, if necessary, when applying at a new company.

Salary, Benefits, and Perks

Base salaries at biopharmaceutical, medical device, and CRO companies are generally higher than comparable jobs in academia. Large companies have established pay scales to ensure equity across the organization. Small, entrepreneurial companies have greater flexibility and may offer higher salaries to attract suitably qualified, new employees. Salaries are reviewed and adjusted annually based on the employee's performance, along with cost-of-living adjustments. In companies that meet their corporate goals, employees who perform well can expect annual increases in their base pay of 1%–7%.

In addition to base salaries, whether the pay scales are constrained or not, these companies supplement an employee's income with other types of cash incentives. The guidelines for bonus programs vary widely, but in most companies clinical workers qualify for an annual cash bonus of 5%–20%, depending on their rank and their performance. Privately owned companies are typically more generous in their bonus programs, to compensate for a lack of stock ownership.

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In publically traded companies, the bonus structure may be divided between cash awards and stock options. Stock options give employees the opportunity to become a partial owner in the company, which historically has been viewed as another way to encourage employee performance. In small, start-up companies that subsequently do well, the value of stock shares may increase significantly and represent a major portion of the employee's income. However, employees typically must wait several years before they are allowed to exercise their options, during which time the stock value may have fluctuated significantly or be of no net value.

Public companies may also offer their employees the opportunity to purchase stock as part of a savings plan. If the company and stock performance are good, the value of these shares may increase more swiftly than other investment programs. In addition, by purchasing stock, the employee becomes a stockholder with all the privileges of other stockholders.

In addition, most healthcare companies offer generous retirement plans and medical insurance benefits. As an added incentive to participate in these plans, many companies match the employee's contributions to the retirement plan and defray a significant portion of the cost of health insurance. Altogether, the cash equivalent of these employee benefit programs (i.e., bonuses, stock, savings, retirement, and insurance) can equal 40%–60% of the employee's base pay.

As an added incentive to attract new clinical workers, companies often offer additional financial assistance. Because cash bonuses are awarded at the end of a year's service when their performance is assessed, new employees must wait a full year before receiving their first bonus. To compensate for this delay, clinical job candidates may be offered a one-time signing bonus which is awarded to them when they begin their employment. In addition, if the new employee must move to a new location to accept the job, the company often offers relocation assistance. Based on the job level and the urgency in hiring a desirable candidate, the relocation package may cover moving expenses, temporary housing costs, and the real estate costs of selling and purchasing a home.

Drug, medical device, and CRO companies set rules for how much time employees may take off and monitor time off more closely than academic and entrepreneurial employers. Some companies set separate rules for vacation time, sick days, and personal leave; others lump all of these categories together under one "paid time off" heading. New employees are typically awarded a total of 3 weeks of annual paid time off. With

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increased years of service, additional days of paid leave are usually added to the annual allotment.

Large and mid-size companies also offer their workers a number of other benefits to make the work environment pleasant and encourage employees to do their best. Common fringe benefits include a subsidized on-site cafeteria, generous family leave provisions, and (for employees who wish to continue their education while working) tuition reimbursement. Some companies also provide an on-site fitness center, subsidize daycare, and match the employee's donations to charitable organizations.

Clinical workers at biopharmaceutical, medical device, and CRO companies work in pleasant office space with all the tools needed to do their job. Even at small companies, they benefit from frequently upgraded office equipment, software, and communications devices. In addition, the companies cover the costs and make the arrangements for business-related travel and on-the-job training programs.

Finally, these companies, because they are in the healthcare business, foster "work-life balance" as a core value. However, like most things in life, what you get out of your job depends on what you put into it. The high visibility and importance of clinical work offers clinical workers greater opportunities to be significantly rewarded, but only if they work hard, do their jobs well, and achieve difficult goals. Such workers have certain personal qualities in common.

PERSONAL QUALIFICATIONS FOR CLINICAL POSITIONS

The chapters in Part II of this book discuss the specialized types of work conducted in an industrial clinical department and the qualifications that are especially relevant to that job category. But hiring managers look for a few personal qualifications in all clinical job applicants.

Team Work

Conducting a clinical study or managing a clinical development program requires the coordinated effort of many people, each of whom makes important contributions. Clinical departments therefore organize their work in teams and manage the teams in a matrix that makes clinical workers accountable both to their team leader and their functional unit supervisor.

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BOX 1-2. *Summary of Clinical Job Qualifications*

- Work effectively as part of a team
- Take initiative and work interdependently
- Good interpersonal skills
- Effective written and verbal communication skills
- Able to meet deadlines and a sense of urgency
- Able to multitask
- Able to adjust to shifting priorities
- Able to work under defined rules and regulations
- Detail-oriented
- Show good judgment
- Perseverance and persistence
- Satisfied with long-term successes

The work environment is collaborative. If a clinical study or project is to succeed, the team must work cooperatively, sharing information, lending assistance, and solving problems together. Each person not only contributes his or her particular expertise but also coordinates that work with the contributions of other team members.

Whether the team is making plans, carrying out assigned tasks, or solving problems, each team member is expected to actively participate. Discussions may take place in formal team meetings, casual hallway conversations, or electronic messages. Good team members listen actively, ask constructive questions, contribute useful information, and volunteer their services if appropriate. They also share credit, acknowledge the contributions of others, and support the team rather than seeking personal credit at the expense of the team or other team members.

Problem solving is often a shared responsibility, even if the problem comes from one specific technical specialty. The problem and how it is solved may have an impact on the progress of the other team members' efforts. Good clinical workers consider their coworkers' input. Often, the best solution comes from a team member, who is not expert in that field, asking a simple question or making a straightforward observation.

Clinical teams work under constant pressure imposed by time constraints, high expectations, and unforgiving medical conditions.

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Inevitably, there are occasional conflicts, but high-performing teams have participants who "work the problem" and avoid placing blame or simply complaining. This requires good interpersonal skills.

Interpersonal Skills

Not everyone who works in a clinical department is an extrovert or "the life of the party." In fact, most clinical workers, given their preference, would work quietly at their desk, avoid conflicts, and take responsibility for solving their own problems. Nevertheless, good clinical team members develop a rapport with their coworkers, value their coworkers' contributions, and earn their coworkers' respect.

In the give-and-take process of solving difficult problems, the team members on high-performing clinical teams focus on the problem, are sensitive to their coworkers' feelings, and engage everyone in the discussion. They realize that their coworkers have a range of personalities and viewpoints, and everyone's perspective is valuable. In addition, good clinical workers sincerely care about others, are good listeners, and offer well-chosen words of support. They foster trust, earn a reputation for being fair, and are easily approachable.

Clinical teams also value coworkers who have a positive, can-do attitude, see obstacles as a challenge, and work hard to overcome them. Valued clinical workers also offer helpful, constructive suggestions and are able to receive criticism gracefully. Many have a pleasant sense of humor.

Clinical teams often operate globally and may include team members representing diverse backgrounds, cultures, and languages. Harmonizing clinical work in such a multinational environment requires not only good interpersonal skills but also knowing how to communicate effectively.

Communication Skills

All clinical workers must be able to express themselves clearly in writing and orally. Their success, both individually and as a team, depends upon relaying accurate and unambiguous information to coworkers and understanding the information they receive from others. Written communications may be short, informal messages sent electronically, or long,

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formal documents such as regulatory submissions and clinical study reports. A considerable amount of communication in clinical departments takes place orally—discussions in team meetings, telephone conversations, conference calls, and formal presentations to senior management groups.

Whether their communications are formal or informal, clinical workers are expected to exchange information clearly, concisely, and in a timely manner. The most effective workers express their views objectively and defend their point of view without offending others. In discussions, they evaluate and accommodate other points of view to help the clinical team make the best decisions and take the best course of action.

This can be especially challenging when team members are spread across different time zones and cultures, require translations to other languages, and rely on electronic communication tools rather than face-to-face interactions. To understand and be understood under these conditions requires not only accommodating different personality types, a high level of communication skill, and cultural sensitivity, but also a great deal of planning.

The most effective clinical workers are proactive in communicating with others and act on the information they receive. They inform others by stating clearly what they are doing and respond quickly and appropriately to requests from others. Most importantly, they ensure that all stakeholders are informed and engaged. With so many people involved in the complicated process of running clinical studies (e.g., team members, clinical investigators, contractors, vendors, and internal management), clinical workers must be nimble in facilitating the flow of information as they conduct their work.

Multitasking and Flexibility

Although most clinical work is highly structured and must comply with strict regulatory requirements, clinical workers are constantly reacting and adjusting to a very dynamic work environment, and their workday is anything but routine. (Examples of these workday dynamics are included in the chapters that describe specific clinical jobs.) A scientific breakthrough or unexpected clinical results may need to be exploited with urgency. Or, in the course of an ongoing project, a team member may offer a new and

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better plan. New managers or new market conditions may set new priorities. Projects may end prematurely either because of negative data or a shift in business strategy. All of these situations require workers to be flexible in adjusting their work, maintain their level of enthusiasm, and apply their skills to new situations.

Clinical workers prioritize their work based on its importance and urgency, not solely on their personal level of interest. Often, those priorities are imposed by others. Even when the work plans are stable, clinical workers often contribute to several studies simultaneously and must balance their efforts appropriately between tasks. That requires not only a good understanding of the work assignments and flexibility, but also good judgment.

Strategic and Tactical Judgment

At the tactical level, each clinical worker contributes a particular expertise and performs a defined set of tasks in support of the clinical study or development program. In addition, there are important handoffs of work between coworkers: Some workers waiting for others to complete a task before they can start, and then handing their finished work to other workers who are waiting on them.

But clinical workers must also understand the strategic context of these tasks. By knowing the objectives of the study, the overall development program goal, the status of products being developed by competitor companies, and the business factors that are driving their efforts, they are in a much better position to plan their time wisely. They know how their work fits into the big picture and can make the right day-to-day decisions for the good of their team, the company, and the patients. Knowing the strategic goals also helps clinical workers to anticipate problems and mitigate risks.

Clinical workers are critical, analytical thinkers. They are accustomed to making sound, science-based decisions. However, they must also show good judgment when making operational decisions, following procedures, and interacting with other people. They must know the right thing to do, the right time to do it, and how to do it the right way, even when the work is difficult or unappealing. Sometimes, that means having the courage to "speak to power" and sometimes it is simply being diligent, complying with rules, and minding the details.

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Rules and Details

Clinical studies of experimental drugs and medical devices are heavily regulated, because there are no shortcuts when it comes to human safety. Clinical workers have a keen sense of ethics and are committed to ensuring patient welfare. They know, accept, and comply with a multitude of regulations, processes, and procedures associated with patient care.

Regulatory agencies also set the data requirements for establishing the efficacy, safety, level of risk, and performance of a new medical product. Clinical workers realize that their work is pointless if their clinical study is flawed and the data they collect do not meet those regulatory requirements.

For both patient welfare and data integrity, the devil is in the details and there are lots of them. Precision, accuracy, completeness, and consistency are characteristic work habits of a good clinical worker.

Taking Initiative

Clinical studies are marathons not sprints. Good clinical workers pace their work, avoid distractions from their targeted goals, and persist despite unanticipated setbacks. They are highly motivated "self-starters" who can maintain their enthusiasm even when trying to solve difficult problems or accepting disappointing study results.

Developing a new drug or medical device means that the team is constantly exploring unknown scientific and medical frontiers. Clinical workers are continually grappling with medical conditions (and complications) that no one has seen before and for which there is no established course of action. Successful clinical teams work as a unit to adapt previous experiences to new situations, prepare for the unexpected, and creatively solve new problems. Good clinical team members therefore undergo a continual process of self-education. They have a natural curiosity and the ability to learn new concepts as they practice and push the boundaries of their craft.

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