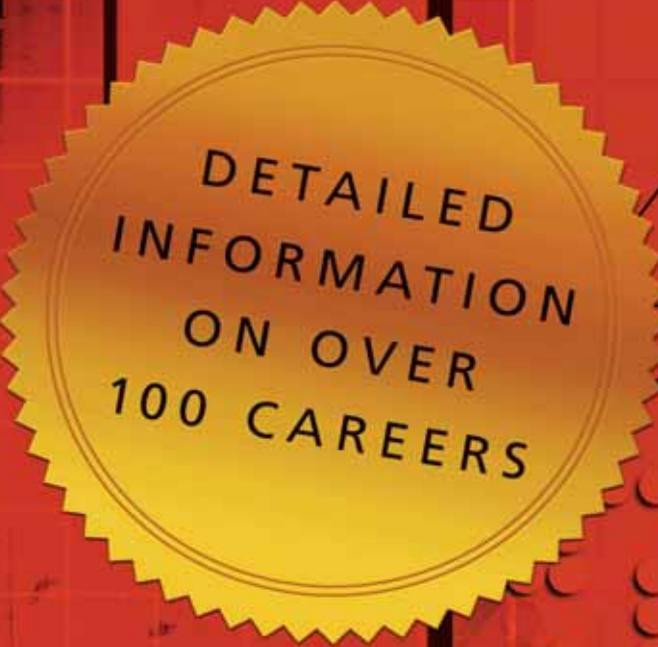


CAREER OPPORTUNITIES in BIOTECHNOLOGY and DRUG DEVELOPMENT



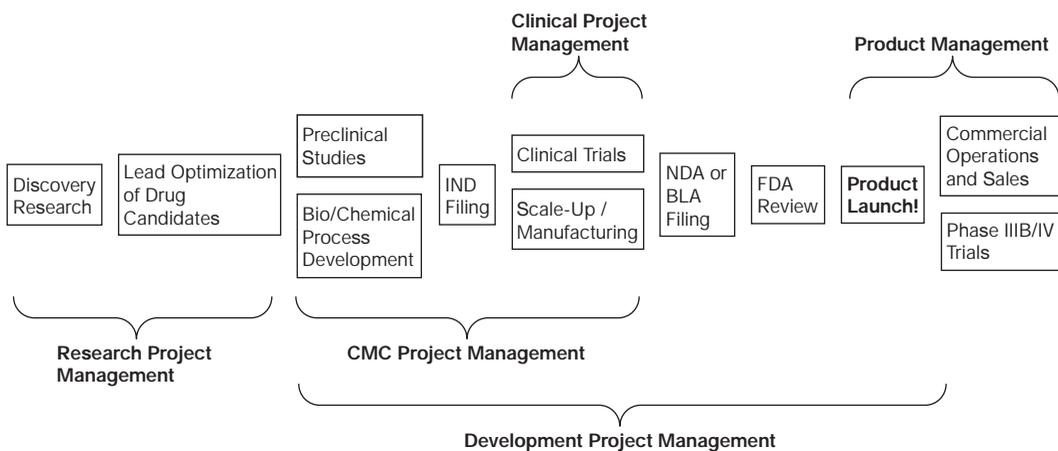
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Project Management

The Product Development “Orchestra Conductors”



DO YOU PREFER TO THINK ABOUT THE BIG PICTURE rather than specialize in a particular scientific discipline? Do you enjoy facilitating the decision-making process and helping to define options by pulling together information from the many groups working on a project? Would you like to serve as the highly visible, primary representative of a project? If so, project management might be the career for you. It requires exceptionally good communication, interpersonal, and diplomatic skills, as well as the ability to manage people without having direct authority over them. You must be able to view a project as a whole while also possessing the technical know-how needed to remove obstructions that might impede project development.

The three most important components of project management are communication, communication, and communication.

THE IMPORTANCE OF PROJECT MANAGEMENT IN BIOTECHNOLOGY AND DRUG DEVELOPMENT

The project management role in biotechnology was created because of the need for someone to coordinate the activities of the many scientific disciplines that are frequently involved in projects. Project managers ensure that projects are moving forward according to pre-established timelines, scope, and budgets. A project manager works as part of a team of people that also includes technical specialists. The manager does not have direct authority over these functional team members; instead, he or she helps to coordinate the tasks of the project so that the team works more effectively and efficiently.

Project managers take part in the decision making but are not the decision makers.

This close involvement with the team members requires the project manager to learn about different departments, their interrelationships, and how products are developed. A project manager needs to be familiar with many diverse technical areas and essentially becomes a Jack or Jill of all trades.

CAREER TRACKS: PROJECT MANAGERS AND PROJECT TEAM LEADERS

The titles and corresponding roles of people in project management vary depending on the size and type of company. For the sake of simplicity, discussion here is limited to the roles of project managers and project leaders.

Project Managers

In therapeutic drug discovery and development companies, the vast majority of project managers handle drug development programs that are in, or are approaching, clinical trials. There are also an increasing number of research project managers, who work in earlier stages of drug development, including early discovery research, late-stage research, and preclinical projects. In addition to the program-wide project managers, there can also be project managers who are dedicated specifically to functional areas that tend to be especially complex, such as clinical research and manufacturing. These positions can often serve as a “training ground” that can lead to an eventual role as a program project manager.

Not all project managers work in drug development companies. Project managers are also needed in life sciences companies that develop products such as instruments, reagents, tools, diagnostics, technology platforms, and medical devices (see Chapter 2).

The roles and responsibilities of project managers depend on the company, project, and product, and they range from recording meeting minutes to leading an entire project. In general, however, the project manager has a more tactical or operational role and serves as a team member with project management responsibilities.

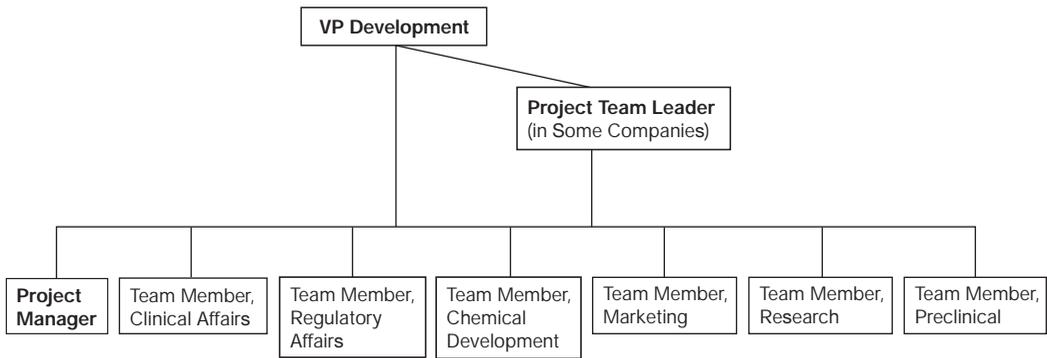


Figure 9-1. Typical team structure for PM.

Project Team Leaders

Project leaders have a more global and strategic role than project managers (see Fig. 9-1). They may be responsible for a program that includes the entire development and testing process of a drug candidate. They communicate the vision and inspiration that drive the project goals, and they ensure that the company's operating values are guiding the project teams. They provide scientific and business leadership and are typically high-ranking, influential people who can speak with authority about the project. Project leaders are frequently M.D.s or Ph.D.s and may be in upper management (e.g., as high as Vice President of Clinical Research). The person designated as project leader can be changed with the stages of product development. For example, a senior research scientist can be the project leader until the drug is in the clinical stage, after which the project leader position shifts to a clinician or senior project manager. Project leaders tend to have project managers on their team, but some smaller companies do not have both project leaders and project managers.

PROJECT MANAGEMENT ROLES AND RESPONSIBILITIES

The roles and responsibilities of project managers or project leaders may include the following:

Leadership

Project managers (and primarily project leaders) provide vision and inspiration to the project's members. By conveying enthusiasm for the project to the team, they try to create a more pro-

Project management is about leading with vision and facilitating teamwork. It takes many different disciplines to develop a drug; if they are not coordinated, time and resources can be squandered on unproductive activities.

ductive working environment. The project manager works as a member of the team to help define the strategy, goals, and metrics for the project.

In addition, the project manager helps to define the roles and responsibilities of team members so that they clearly understand what they are supposed to be doing. Project managers help resolve personal and cross-functional conflicts so that the team functions smoothly. They serve as psychological team boosters by listening to individual team members, reassuring them, and motivating them to best fulfill their team functions.

Communication

In most companies, one of the most important roles for project managers is to facilitate communication in many directions—upward to senior management and corporate partners, sideways to project team peers, and downward to the technicians and others who support the project. The team develops the goals, and the project manager, as a representative of the team, presents them to the company.

Meeting Management

Project managers spend a significant percentage of their time scheduling and running meetings, creating agendas, identifying action items, recording the minutes, and sending follow-up messages afterward.

Resource Allocation

Project managers manage project timelines and budgets. They work closely with finance department members to calculate how much money is required to run the project. They track expenditures and adjust the projected budget and staffing requirements as needed over time. One of a project manager's key responsibilities is to anticipate budget or staffing shortfalls that threaten the project, to notify upper management of the risk, and to request additional funding if needed.

Strategy and Decision Management

The project manager tries to ensure that the team addresses cross-functional issues and considers all pertinent information when it makes decisions. He or she facilitates discussions to develop consensus among team members. When a consensus cannot be reached, the project manager sometimes has the responsibility to make the final decision, but he or she also should know when it is appropriate to bring upper management into the discussion. Project managers are expected to represent the views of team members and to communicate relevant issues to upper management.

Risk Mitigation and Contingency Planning

Because of the complexity and difficulty of many projects, there are multiple chances for disaster to strike. Among other things, the project can fail to meet its clinical objective,

supplies can be exhausted during a clinical trial, or senior management can decide to terminate a project. With the team's help, the project manager identifies potential risks, conducts analyses, and develops contingency plans to mitigate those risks so that the team and upper management can assess the probability of success.

Problem Solving

When something goes wrong with a project or when progress stops, the project manager is the person who needs to get things moving again. He or she should either possess enough technical know-how to help resolve the problems or know whom to contact for help. The project manager needs to make sure the functional areas take problems seriously, identify solutions, and act on them.

Alliance Management

In some companies, project managers coordinate projects with corporate partners. They are responsible for promoting good relationships and effective communication with corporate partners to make sure that the goals of the two companies are aligned and the teams are working together effectively.

Documentation, Processes, and Procedures

Project managers are responsible for creating, maintaining, and documenting development plans, as well as tracking the project's progress. Other management processes that may need to be established and tracked include cost, quality, risk, and procurement.

A TYPICAL DAY IN PROJECT MANAGEMENT

Because of the unpredictability of product development and the broad range of roles and responsibilities in project management, there is no such thing as a "typical day." In general, project managers and project leaders spend most of their time talking to people in the form of one-on-one or group meetings. Time is spent discussing upcoming milestones with team members and addressing any problems with meeting those milestones. If there is an alliance partner or a significant number of team members at a different site, project managers and project leaders may spend time traveling.

A project manager or project leader can expect some of the following activities on a typical day:

- Preparing project reports, budgets, timelines, and analyses, and presenting these reports to project members and senior management.
- Arranging meetings, creating presentation materials, recording meeting minutes, and distributing minutes after meetings.

- Meeting one-on-one with project members and department heads to solve problems and ensure that priorities are uniformly established.
- Managing alliances with corporate partners, traveling, and networking.

SALARY AND COMPENSATION

In general, the salary of a project manager is comparable to that of a discovery research scientist, which is concomitant with title and responsibility, years of experience, and expertise. Consultants, vice presidents, and project leaders can earn higher incomes and are often at the top of the pay scale. Project managers and project leaders who have overseen successful product developments should be able to demand higher compensation.

How is success measured?

Success is usually subjectively measured by how efficiently the project moves forward, the quality of execution, and how well the team functions together. Other metrics include project success, timeliness, and how well the project remained within budget. Project managers should gain satisfaction from the success of the team as opposed to recognition for their own individual contributions.

PROS AND CONS OF THE JOB

Positive Aspects of a Career in Project Management

- Project management is a very dynamic job; there is “never a dull moment.”
- It provides an excellent opportunity to discover the ins and outs of product development, including operational, financial, clinical, scientific, regulatory, and legal issues. Successful navigation of these waters can lead to other career opportunities.
- A project manager interacts with people throughout the company... all the way from laboratory scientists to the CEO.
- Senior project managers and project leaders may be highly visible in a company and have decision-making responsibilities.
- Managing complex and technically difficult projects can be intellectually stimulating.
- Project management does not require bench work. There are usually no direct reports to manage, either.

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- Seeing a project to its completion and watching a team perform well as a consequence of one's efforts can be highly rewarding.

The Potentially Unpleasant Side of Project Management

- The challenge of influencing people without having direct authority over them can be frustrating. Much time is spent convincing and coaxing team members (see “Greatest Challenges”). Senior managers may make strategic decisions without the project manager's involvement.
- Frequent travel may be required.
- Scientific expertise might be sacrificed to the time-hungry demands of becoming familiar with many disciplines across the company.
- Long-term projects can try one's patience and sap enthusiasm.
- Daily progress can be hard to measure—project management is unconventional and exciting but also may lead to little immediate gratification.
- When things go well, the functional team members usually receive the credit. The reverse, however, is not true: When things go badly, project managers frequently suffer the blame. Many things can go wrong, including things beyond the project manager's control, and projects can easily fail and be terminated.
- Day-to-day activities such as arranging meetings, writing minutes, etc., can be mundane. There can be a lot of paperwork.
- It can be frustrating to manage alliances when corporate partners have different cultural values.
- If there is bad news, it is often the project manager's job to tell the team.

Project managers have much of the responsibility and little of the authority.

THE GREATEST CHALLENGES ON THE JOB

Responsibility without Authority

The biggest challenge is the project manager's lack of direct authority over the team members he or she manages. When team members have aims and responsibilities that prevent them from contributing effectively to the project, the project manager cannot order them to change their agendas. He or she can try to persuade them by explaining the corporate culture and the priorities or overall goals of the project or company, and by convincing them that their work is needed for a particular function. The project manager can also resort to speaking with a team member's manager or with upper management. All of these options require very good interpersonal and diplomatic skills. Much time is spent coaching, reassuring, and motivating people.

Perseverance

Maintaining a consistent point of view and keeping team members motivated on lengthy projects can be challenging. Tenacity should not be underestimated as a key personal attribute needed for success.

Diplomacy

Project managers need to be able to make or facilitate decisions based on varied points of view without causing conflict. Maintaining positive team relationships while working to advance the project can sometimes be a delicate balancing act.

There are great project managers with mediocre scientific skills, but there are no great project managers with mediocre interpersonal skills!

Objectivity

Whereas project managers need to keep the team motivated and excited about the project, it is important that they also objectively evaluate the project's potential. As driver of the project's decision management, knowing when to end a project is just as valuable as deciding to push forward with it.

TO EXCEL IN PROJECT MANAGEMENT...

Years of Experience

Ultimately, the combination of exceptionally good interpersonal skills and years of experience is what separates the good from the great. With experience, project managers develop the ability to anticipate potential issues before they arise. They also cultivate a good understanding of, and appreciation for, the different functional areas and their cross-functional interdependencies.

You won't be a successful project manager if you think you know everything.

Are You a Good Candidate for Project Management?

People who flourish in project management careers tend to have...

Superb interpersonal skills. This is probably the most important factor for success in project management. Good interpersonal skills allow you to develop positive, collaborative, and productive relationships with team members and other coworkers (see Chapter 2).

Excellent communication and interpersonal skills are essential.

Excellent communication skills. Many of a project manager's duties center around the ability to communicate with multidisciplinary team members. You must be able to speak and write clearly and in such a way that you can accomplish your goals while avoiding being confrontational or alienating individuals.

The ability to simultaneously see the big picture and pay attention to the details. Understanding and thinking strategically about a project as a whole is as important as taking care of the minutiae.

An ability to foster a collaborative and positive work environment. Sometimes success is measured by how well a team worked together. The ability to understand and tolerate different perspectives and to be able to formulate and implement a plan that is agreeable to the team helps foster a collaborative environment... after all, happy coworkers are more productive!

A "team player" attitude. This is a must in project management (see Chapter 2). Project managers tend to be gregarious, yet willing to face disagreement for the good of the team.

Excellent organizational and time management skills. Often project managers work on multiple assignments simultaneously. Good organizational and prioritization skills must be applied to save time, manage the volumes of information, and keep track of technical details.

Strong leadership skills. It helps to be assertive, action-oriented, and self-confident if you want to convince your fellow team members to move projects forward, but you also need to be diplomatic at the same time.

Proactive and analytical thinking skills. You must be able to anticipate difficulties and develop contingency plans before problems become obstacles. It helps to be analytical, consistent, and level-headed.

Creative problem-solving skills. Project managers are constantly faced with the need to solve problems. The ability to think objectively and flexibly and to quickly evaluate alternative solutions makes it easier to overcome technical obstacles and internal conflicts that might slow a project's progression.

Good judgment when making difficult decisions. Often there is not enough information available to make the best-informed decisions, so you need wisdom and intuitive judgment to select the most promising choices based on limited data.

You should probably consider a career outside project management if you are...

- Frequently unable to move forward because you get stuck on details.
- Too aggressive.
- A micromanager or someone who needs to be micromanaged.
- Someone who tends to take disagreement too personally.
- A person who needs immediate gratification and personal recognition.
- Unable to function within an unstructured environment or with uncertain outcomes.
- A person who manages by using negative reinforcement.
- Too easygoing.
- Someone who likes to work alone.

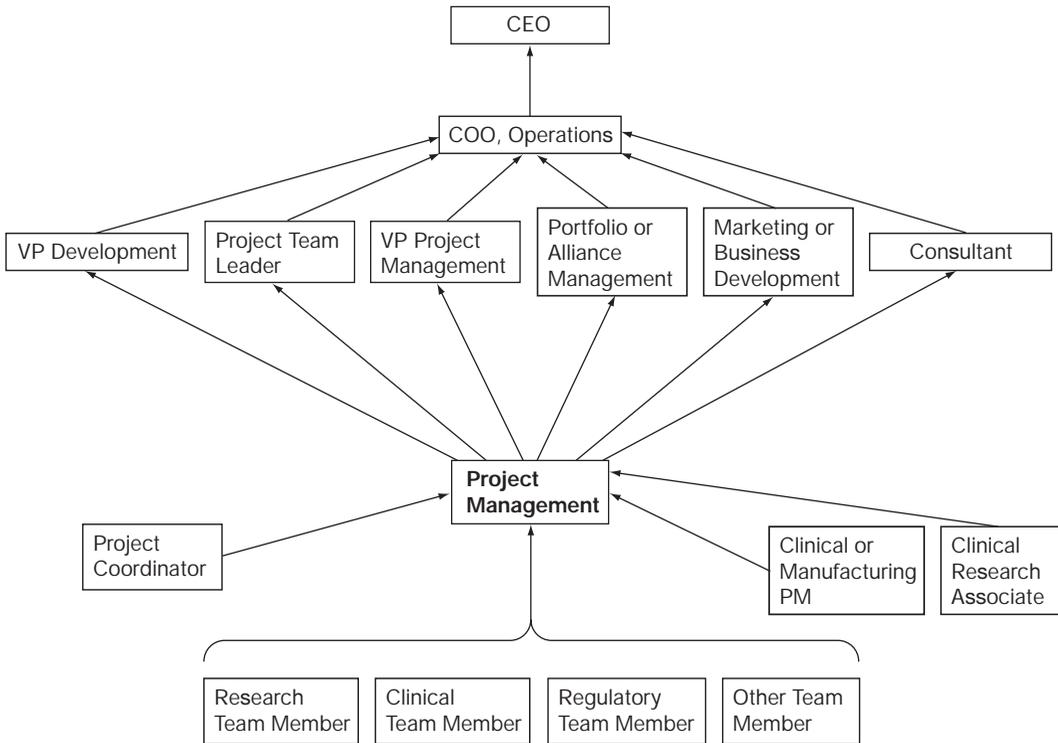


Figure 9-2. Project management career ladder.

PROJECT MANAGEMENT CAREER POTENTIAL

Project managers become technically knowledgeable in multiple functional areas, so this occupation can lead to a diverse set of career options (Fig. 9-2). Within project management, career possibilities include Project Team Leader and Vice President of Project Management. Project managers with more general skills often go into consulting, business development, alliance management, organizational learning, or portfolio management. Those with more technical expertise can transfer to positions as functional heads of product or clinical development, operations, manufacturing, or regulatory affairs.

Project management experience is excellent preparation for eventual COO/CEO leadership roles. Project managers hone their organizational skills, become adept at motivating and managing people, and understand how to move a product through development and into the market.

Job Security and Future Trends

The demand for talented project managers is strong and is predicted to increase. As the biotechnology industry has shifted its focus toward more development-related activities, project management has become a more visible and marketable discipline. Companies

have recognized the valuable role of project management in expediting and coordinating product development. The combination of highly sophisticated technical knowledge and strong interpersonal skills gives project managers a unique skill set, so in general, they enjoy relatively long-term job security. It should be noted, however, that a project manager in a smaller company could be an early victim of layoffs during economic downturns.

LANDING A JOB IN PROJECT MANAGEMENT

Experience and Educational Requirements

Project management requires a broad technical and operational background and strong science acumen. A project manager must be technically credible, provide reasonable input, ask appropriate questions, and be able to resolve problems strategically and creatively. For these reasons, a project management position typically requires at least three years of industry experience to develop insight into how teams work. Most project managers have previously been team members from one of the various functional areas such as discovery research, manufacturing, process development, clinical research, or regulatory affairs. Project leader positions require extensive involvement in product development as both a team member and a manager.

An advanced degree is not essential for a job in project management, but it can be extremely helpful. Most project managers have a master's or Ph.D. degree, and some have M.B.A. or R.N. degrees. Qualifications depend in part on the requirements of a project. An early discovery project, for example, might require a Ph.D. degree, whereas an R.N. degree might be more useful for a clinical project manager. Project leaders are typically Ph.D.s or M.D.s.

Certificates in project management can be obtained from many universities and from the Project Management Institute. Although such certificates are desirable, exposure to the drug development process is far more valuable.

Paths to Project Management

- Serve as a team member in one of the functional areas; this is by far the most common route to project management. Learn from a project manager who is willing to mentor you.
- Consider working as a project coordinator. This entry-level position leads to a project management role. Project coordinators assist project managers with tasks such as arranging meetings. By showing that you can facilitate productive meetings (a skill that can be learned), you have the chance to demonstrate leadership ability.
- Consider joining a clinical research organization (CRO) if you are interested in clinical project management. Working at a CRO provides excellent clinical research exposure and allows a transition to a job in a drug discovery company. CROs often hire Ph.D.s

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with clinical experience to be group leaders or project managers. Those with undergraduate or nursing degrees can become clinical research associates (CRAs) or project coordinators; both of these jobs lead to career tracks in project management. If you are still in graduate school, try to gain some exposure to clinical trials.

- Attend project management society meetings and conferences; they are good places to network. Make as many contacts as you can. As with all careers, the more people you know, the more likely someone will open a door for you.
- Gain as much experience managing people as possible. Demonstrate the ability to be a level-headed, strategic thinker, and learn how to give lucid presentations.
- Obtain as much experience in drug discovery and development as you can. Become familiar with the internal and external factors that affect these processes, including business and product development issues. Take courses in drug discovery and development.

RECOMMENDED TRAINING, PROFESSIONAL SOCIETIES, AND RESOURCES

Courses and Certificate Programs

Project management certificates are offered in most local universities and can also be found by conducting on-line searches. Programs that are particularly recommended are offered by The Project Management Institute (www.pmi.org) and George Washington University. Barnett Educational Services (www.barnettinternational.com) offers classes that are designed specifically for people interested in clinical trials and drug development.

Project Management Societies and Resources

Project Management Institute (PMI), www.pmi.org
 Project Managers in Pharmaceuticals (San Francisco nonprofit), www.projmgr.org
 Project Connections, www.projectconnections.com

Drug Discovery and Development Societies

Association of Clinical Research Professionals, www.acrpnet.org
 Drug Informational Association (DIA), www.diahome.org. The DIA has a strong project management group within the organization. Their annual meeting is a good place to make contacts and learn about project management in biotechnology and pharmaceutical companies.

Books and Magazines

PMI offers several books about project management.

Covey S.R. 2004. *The 7 habits of highly effective people: Powerful lessons in personal change*. Free Press, New York.

Other Suggestions

Consider taking classes in conflict resolution and public speaking. Become a member of Toastmasters International, www.toastmasters.org.

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