实用药学英语

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西南交通大学出版社
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前　言

随着我国“一带一路”倡议和“走出去”战略的提出，国家对复合型技能型人才的需求与日俱增。与此同时，2019 年国务院印发的《国家职业教育改革实施方案》提出了“三教”（教师、教材、教法）改革的任务，指出“三教”改革落脚点是培养适应行业企业需求的复合型、创新型高素质技术技能人才，目的是提升学生的综合职业能力。基于此背景，本书编者编写了这本针对我国高职高专及应用型本科药学及相关专业学生，突出实用性、应用性，同时符合职业院校学生的英语水平和认知特点的《实用药学英语》教材。

本教材包括药品研发、药品生产、药品使用、用药安全、药品行业相关职业技能和拓展阅读六个模块，每个模块由四至六篇课文组成，每篇课文后都精心设计了词汇、阅读和口语练习。在“课程思政”理念的指导下，选材与任务设计实现了知识性、实用性和育人性的有机统一。编者精心选取教材内容，设计形式各异的练习，旨在让学生熟悉和了解药学领域相关岗位职责和中医药文化，提高学生的英语综合应用能力和分析解决问题的能力，培养学生的批判性思维，涵养他们的文化自信和制度自信，为我国培养具有良好职业素养的复合型、创新型高素质技术技能人才。

本书由酒泉职业技术学院易建红主编并负责全书统稿，范佩芳任副主编。本书在编写过程中，得到了西南交通大学出版社和酒泉职业技术学院的大力支持和帮助，在此表示衷心的感谢。

鉴于编者水平有限，本书不妥之处在所难免，恳请各位读者提出宝贵意见，使本教材能进一步完善。

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The R&D of Drug

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Lesson One　Drug Discovery

It is the mission of pharmaceutical research companies to take the path from understanding a disease to bringing a safe and effective new treatment to patients. Scientists work to piece together the basic causes of disease at the level of genes, proteins and cells. Out of this understanding emerge "targets," which potential new drugs might be able to affect. Researchers work to:

• validate these targets

• discover the right molecule (potential drug) to interact with the target chosen

• test the new compound in the lab and clinic for safety and efficacy and gain approval and get the new drug into the hands of doctors and patients.

It takes about 10 – 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. The average cost to research and develop each successful drug is estimated to be $800 million to $1 billion. This number includes the cost of the thousands of failures: For every 5,000–10,000 compounds that enter the research and development (R&D) pipeline, ultimately only one receives approval. These numbers defy imagination, but a deeper understanding of the R&D process can explain why so many compounds don't make it and why it takes such a large, lengthy effort to get one medicine to patients. Success requires immense resources – the best scientific minds, highly sophisticated technology and complex project management. It also takes persistence and, sometimes, luck.

1. Pre-discovery

Understand the Disease

Before any potential new medicine can be discovered, scientists work to understand the disease to be treated as well as possible, and to unravel the underlying cause of the condition. They try to understand how the genes are altered, how that affects the proteins they encode and how those proteins interact with each other in living cells, how those affected cells change the specific tissue they are in and finally how the disease affects the entire patient. This knowledge is the basis for treating the problem. Researchers from government, academia

and industry all contribute to this knowledge base. However, even with new tools and insights, this research takes many years of work and, too often, leads to frustrating dead ends. And even if the research is successful, it will take many more years of work to turn this basic understanding of what causes a disease into a new treatment.

Target Identification

Choose a molecule to target with a drug. Once they have enough understanding of the underlying cause of a disease, pharmaceutical researchers select a "target" for a potential new medicine. A target is generally a single molecule, such as a gene or protein, which is involved in a particular disease. Even at this early stage in drug discovery it is critical that researchers pick a target that is "drugable," i.e., one that can potentially interact with and be affected by a drug molecule. Target validation test the target and confirm its role in the disease After choosing a potential target, scientists must show that it actually is involved in the disease and can be acted upon by a drug. Target validation is crucial to help scientists avoid research paths that look promising, but ultimately lead to dead ends. Researchers demonstrate that a particular target is relevant to the disease being studied through complicated experiments in both living cells and in animal models of disease.

2. Drug Discovery

Find a promising molecule (a "lead compound") that could become a drug. Armed with their understanding of the disease, scientists are ready to begin looking for a drug. They search for a molecule, or "lead compound," that may act on their target to alter the disease course. If successful over long odds and years of testing, the lead compound can ultimately become a new medicine. There are a few ways to find a lead compound. Nature: Until recently, scientists usually turned to nature to find interesting compounds for fighting disease. Bacteria found in soil and moldy plants both led to important new treatments, for example. Nature still offers many useful substances, but now there are other ways to approach drug discovery. De novo: Thanks to advances in chemistry, scientists can also create molecules from scratch. They can use sophisticated computer modeling to predict what type of molecule may work. High-throughput Screening: This process is the most common way that leads are usually found. Advances in

robotics and computational power allow researchers to test hundreds of thousands of compounds against the target to identify any that might be promising. Based on the results, several lead compounds are usually selected for further study. Biotechnology: Scientists can also genetically engineer living systems to produce disease-fighting biological molecules.

Early Safety Tests

Perform initial tests on promising compounds lead compounds go through a series of tests to provide an early assessment of the safety of the lead compound. Scientists test absorption, distribution, metabolism, excretion and toxicological (ADME/Tox) properties, or "pharmacokinetics," of each lead. Successful drugs must be:

absorbed into the bloodstream,

distributed to the proper site of action in the body,

metabolized efficiently and effectively,

successfully excreted from the body,

demonstrated to be not toxic.

These studies help researchers prioritize lead compounds early in the discovery process. ADME/Tox studies are performed in living cells, in animals and via computational models.

Lead Optimization

Alter the structure of lead candidates to improve properties. Lead compounds that survive the initial screening are then "optimized," or altered to make them more effective and safer. By changing the structure of a compound, scientists can give it different properties. For example, they can make it less likely to interact with other chemical pathways in the body, thus reducing the potential for side effects. Hundreds of different variations or "analogues" of the initial leads are made and tested. Teams of biologists and chemists work together closely: The biologists test the effects of analogues on biological systems while the chemists take this information to make additional alterations that are then retested by the biologists. The resulting compound is the candidate drug. Even at this early stage, researchers begin to think about how the drug will be made, considering formulation (the recipe for making a drug, including inactive ingredients used to hold it together and allow it to dissolve at the right time), delivery mechanism (the way the drug is taken – by mouth, injection, inhaler) and large-scale manufacturing (how you make the drug in large quantities).

Preclinical Testing

Lab and animal testing to determine if the drug is safe enough for human testing. With one or more optimized compounds in hand, researchers turn their attention to testing them extensively to determine if they should move on to testing in humans. Scientists carry out in vitro and in vivo tests. In vitro tests are experiments conducted in the lab, usually carried out in test tubes and beakers ("vitro" is "glass" in Latin) and in vivo studies are those in living cell cultures and animal models ("vivo" is "life" in Latin). Scientists try to understand how the drug works and what its safety profile looks like. The U.S. Food and Drug Administration (FDA) requires extremely thorough testing before the candidate drug can be studied in humans. During this stage researchers also must work out how to make large enough quantities of the drug for clinical trials. Techniques for making a drug in the lab on a small scale do not translate easily to larger production. This is the first scale up. The drug will need to be scaled up even more if it is approved for use in the general patient population. At the end of several years of intensive work, the discovery phase concludes. After starting with approximately 5,000 to 10,000 compounds, scientists now have winnowed the group down to between one and five molecules, "candidate drugs," which will be studied in clinical trials.

Glossary

validate	['vælɪˌdeɪt]	*vt*. 使生效
candidate	['kændɪˌdeɪt]	*n*. 候选
efficacy	['efɪkəsɪ]	*n*. 功效
alter	['ɔ:ltə]	*vi*. 改变；更改
approval	[ə'pru:vl]	*n*.（正式的）批准
identification	[aɪˌdentɪfɪ'keɪʃən]	*n*. 认同
compound	['kɒmpaʊnd]	*n*. 化合物
absorption	[əb'zɔ:pʃən]	*n*. 吸收
defy	[dɪ'faɪ]	*vt*. 公然违抗
distribution	[ˌdɪstrɪ'bju:ʃən]	*n*. 分布
lengthy	['leŋθɪ]	*adj*. 漫长的

excretion	[ɪkˈskriːʃən]	*n*. 排泄；排出
properties	[ˈprɒpətɪz]	*n*. 性能
toxicological	[ˌtɒksɪkəˈlɒdʒɪkl]	*adj*. 毒理学的

Phrases and Expressions

vitro test　体外试验
vivo tests　活体试验
interact with　与……相互作用
lead optimization　先导化合物的优化
be scaled up　扩大规模
armed with　以……为武器

Reading Skills Exercise

1. Read the text and finish the quiz.

1. On average, it takes _____ years to do the discovery research and testing to bring a new drug to the market.

A. 6 – 9

B. 9 – 12

C. 12 – 15

D. 15 – 18

2. Which one is NOT a reason promising compounds might be abandoned?

A. Safety/toxicity issues.

B. Poor absorption or ineffectiveness.

C. Manufacturing difficulties.

D. Limited market potential.

3. What is the purpose of pre-clinical testing?

A. Verify that a drug is sufficiently safe and effective to be tested in humans.

B. Undergo preliminary testing in healthy humans to monitor the effects of the drug.

C. Create a basic outline for the larger scale future tests on a widespread population.

D. A and B.

4. Which is the primary goal/major milestone of preclinical development?

A. Filing an IND application with the FDA.

B. Identifying the target population for the lead compound that is being developed.

C. To determine anticipated revenue.

2. Rank the order of discovering a new drug.

A. understand the disease　B. target identification　G. preclinical test

C. early safety test　D. target validation　F. drug discovery

E. lead optimization

Step1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7

Speaking

Read the story *Chinese scientist Tu Youyou and Artemisinin* and share with your partners on what you've learned from this story.

中国故事——屠呦呦和青蒿素

2015 年 10 月 5 日，从瑞典斯德哥尔摩传来令人振奋的消息:中国女科学家屠呦呦获得 2015 年诺贝尔生理学或医学奖。理由是她发现了青蒿素，这种药品可以有效降低疟疾患者的死亡率。屠呦呦是第一位获得诺贝尔科学奖项的中国本土科学家、第一位获得诺贝尔生理医学奖的华人科学家。

屠呦呦获得了诺贝尔生理学或医学奖，填补了我国无诺贝尔科学奖的空白。她将中医中药推向了世界，她将民族的变成世界的。过去，包括很多中国人在内的国内外学者专家，都批评中医中药为伪科学。屠呦呦用诺贝尔医学奖粉碎了他们对中医中药的攻击，奠定了中医中药在世界医学领域的地位。屠呦呦是民族的功勋、佼佼者，她对科学的贡献是卓著的。

40 年前的科研条件和环境可想而知，屠呦呦要从医药中寻找抗疟新药谈何容易？屠呦呦和她的团队，克服重重困难，可谓历经千辛万苦。失败了，推掉重来，经历了无数次的实验。在失败面前，他们不言弃，始终执着地追

求。屠呦呦被称为“三无教授”，她毫不在乎，兢兢业业，对科学执着追求，锲而不舍。为了检验药物的效果，屠呦呦甚至亲自口服药物，尝试药物在自己身上的反应，以做到保证药物的万无一失，屠呦呦的肝脏因此受到了损伤，牺牲了自己的健康，目的就是换来大家的健康，换来人类的科学进步。屠呦呦与青蒿素之间充满了许多精彩传奇故事，表现了科学家的态度、品质和精神，屠呦呦的精彩故事是一本极好的励志书。必须用好这本书，教育我们的下一代，学习科学家的精神特质，“攻城不怕坚，攻书莫畏难。科学有险阻，苦战能过关。”在困难面前不低头，在荣誉待遇面前不伸手，为着祖国的科学事业默默无闻无私奉献。

Lesson Two Drug Development Process

Before any clinical trial can begin, the researchers must file an Investigational New Drug (IND) application with the FDA. The application includes the results of the preclinical work, the candidate drug's chemical structure and how it is thought to work in the body, a listing of any side effects and manufacturing information. The IND also provides a detailed clinical trial plan that outlines how, where and by whom the studies will be performed. The FDA reviews the application to make sure people participating in the clinical trials will not be exposed to unreasonable risks.

FDA IND Review Team

The review team consists of a group of specialists in different scientific fields. Each member has different responsibilities.

Members	Responsibilities
Project Manager	Coordinates the team's activities throughout the review process, and is the primary contact for the sponsor.
Medical Officer	Reviews all clinical study information and data before, during, and after the trial is complete.
Statistician	Interprets clinical trial designs and data, and works closely with the medical officer to evaluate protocols and safety and efficacy data.
Pharmacologist	Reviews preclinical studies.
Pharmacokineticist	Focuses on the drug's absorption, distribution, metabolism, and excretion processes. Interprets blood-level data at different time intervals from clinical trials, as a way to assess drug dosages and administration schedules.
Chemist	Evaluates a drug's chemical compounds. Analyzes how a drug was made and its stability, quality control, continuity, the presence of impurities, etc.
Microbiologist	Reviews the data submitted, if the product is an antimicrobial product, to assess response across different classes of microbes.

Approval

The FDA review team has 30 days to review the original IND submission. The process protects volunteers who participate in clinical trials from unreasonable and significant risk in clinical trials. FDA responds to IND applications in one of two ways:

Approval to begin clinical trials.

Clinical hold to delay or stop the investigation. FDA can place a clinical hold for specific reasons, including: Participants are exposed to unreasonable or significant risk; Investigators are not qualified; Materials for the volunteer participants are misleading; The IND application does not include enough information about the trial's risks.

A clinical hold is rare. Instead, FDA often provides comments intended to improve the quality of a clinical trial. In most cases, if FDA is satisfied that the trial meets Federal standards, the applicant is allowed to proceed with the proposed study.

The developer is responsible for informing the review team about new protocols, as well as serious side effects seen during the trial. This information ensures that the team can monitor the trials carefully for signs of any problems. After the trial ends, researchers must submit study reports. This process continues until the developer decides to end clinical trials or files a marketing application. Before filing a marketing application, a developer must have adequate data from two large, controlled clinical trials.

Phase 1　Clinical Trial Perform initial human testing in a small group of healthy volunteers

The candidate drug is tested in people for the first time. These studies are usually conducted with about 20 to 100 healthy volunteers. The main goal of a Phase 1 trial is to discover if the drug is safe in humans. Researchers look at the pharmacokinetics of a drug: How is it absorbed? How is it metabolized and eliminated from the body? They also study the drug's pharmacodynamics: Does it cause side effects? Does it produce desired effects? These closely monitored trials are designed to help researchers determine what the safe dosing range is and if it should move on to further development.

Phase 2　Clinical Trial Test in a small group of patients

The researchers evaluate the candidate drug's effectiveness in about 100 to

500 patients with the disease or condition under study, and examine the possible short-term side effects (adverse events) and risks associated with the drug. They also strive to answer these questions: Is the drug working by the expected mechanism? Does it improve the condition in question? Researchers also analyze optimal dose strength and schedules for using the drug. If the drug continues to show promise, they prepare for the much larger Phase 3 trials.

Phase 3 Clinical Trial Test in a large group of patients to show safety and efficacy

The researchers study the drug candidate in a larger number (about 1,000 – 5,000) of patients to generate statistically significant data about safety, efficacy and the overall benefit-risk relationship of the drug. This phase of research is key in determining whether the drug is safe and effective. It also provides the basis for labeling instructions to help ensure proper use of the drug (e.g., information on potential interactions with other medicines). Phase 3 trials are both the costliest and longest trials. Hundreds of sites around the United States and the world participate in the study to get a large and diverse group of patients. Coordinating all the sites and the data coming from them is a monumental task. During the Phase 3 trial (and even in Phases 1 and 2), researchers are also conducting many other critical studies, including plans for full scale production and preparation of the complex application required for FDA approval.

New Drug Application (NDA) submit application for approval to FDA

Once all three phases of the clinical trials are complete, the sponsoring company analyzes all of the data. If the findings demonstrate that the experimental medicine is both safe and effective, the company files a New Drug Application (NDA) – which can run 100,000 pages or more – with the FDA requesting approval to market the drug. The NDA includes all of the information from the previous years of work, as well as the proposals for manufacturing and labeling of the new medicine.

Once FDA receives an NDA, the review team decides if it is complete. If it is not complete, the review team can refuse to file the NDA. If it is complete, the review team has 6 to 10 months to make a decision on whether to approve the drug. The process includes the following:

Each member of the review team conducts a full review of his or her section