

RESEARCH AND DEVELOPMENT TAX CREDIT FOR LIFE SCIENCE FIRMS

Research and development (R&D) Regular Credit and Payoff Tax

offset: The R&D Tax Credit is one of the most lucrative permanent corporate tax benefits in the Internal Revenue Code and remains as such after the sweeping Tax Reform passed in 2017. The U.S. Government addressed inequities in the R&D tax credit rules in 2016. In addition to offsetting federal income taxes, the R&D tax credit can now be used to offset the employer portion of payroll taxes for eligible companies, even if they are not yet profitable. To be eligible for the payroll tax offset, companies must meet the following qualifications, even if they are not taxable:

- Incurred Gross Receipts For Five Years Or Less
- Realized Less Than \$5 Million In Gross Receipts in The Year The Credit Is Taken
- Incurred Qualifying Research Activities and Expenditures
- Employer Participated In Qualified Payroll — Tax Liability

LIFE SCIENCE R&D TAX CREDIT CLAIMS

Federal and state-level R&D Tax Credits can be rewarded for many research activities that Life Science companies perform. The R&D Tax Credit serves to help Life Science firms further innovate and expand by reinvesting these valuable tax credits back into the business.

If you are creating or improving a product or process, either for your customers or even for yourself, you may have activities that can result in R&D Tax Credits. Such Life Science-type activities may include developing new prototype medical devices, drug delivery systems, or pharmaceutical apparatuses or next generation medical devices. Many common medical equipment industry practices performed by both large scale and small scale manufacturers, such as 3D printing, will qualify for the credit under the IRS's definition of R&D.

The development and testing of new pharmaceuticals, therapies, biologics, or other medical compounds are highly qualifying activities that may be eligible for the R&D Tax Credit benefit. With recent law changes, more expenditures than ever before are available to Life Science companies for inclusion in their R&D Tax Credit claims for the very activities that they perform on a daily basis.



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COMMON LIFE SCIENCES ACTIVITIES THAT CAN QUALIFY FOR THE CREDIT:

- R&D Stage One: preclinical/discovery research pharmaceutical activities
- R&D Stage Two: clinical development pharmaceutical activities, including but not limited to initial human trials (Phase I), pilot studies to determine efficacy and safety (Phase II), and expanded clinical trials to gather further evidence (Phase III).
- Development of treatments for rare diseases that affect small populations (i.e., Orphan Drug enhanced credit)
- Designing, prototyping, simulating new or improved formulas, products or processes
- Improving the design of existing formulas, products, medical devices or processes
- Engineering and exploring new formulas, products or processes
- Trial production runs
- Innovative packaging designs
- Designing, prototyping, simulating new or improved products or processes
- Improving the design of existing products or processes
- Performing experiments to validate adequacy of new or improved designs
- Engineering and exploring new products or processes
- Designing, building, and testing of pilot models
- The development of special tooling/fixtures in order to carry out manufacturing processes

Below is a small sampling of pre-clinical and clinical R&D Departments for the Life Sciences Industry:

PRE-CLINICAL POTENTIALLY QUALIFYING DEPARTMENTS	CLINICAL POTENTIALLY QUALIFYING DEPARTMENTS
Biology	Pharmaceutical
Chemistry	Analytical Chemistry
Pharmacology and Toxicology	Biostatistics
Drug Metabolism	Pharmaceutical Technology Development
Protein Discovery	Clinical Research and Development (Phase I, II, and III)
Medical Device Equipment Engineering (R&D)	Medical Device Manufacturing Process Improvement

R&D STUDY APPROACH

Withum maintains a sophisticated team of dedicated R&D Tax Credit specialists, who assist companies in all industries, including Life Sciences. We are committed to helping you file the largest federal and state-level credits for which you are entitled to and are here to take a fresh look at the processes employed to account for qualified research activities and the annual data gathering process. Our team can assist in identifying R&D opportunities and ensuring that you are maximizing your credit potential. Our R&D study approach is tailored to provide you with taxing authority-ready documentation to support, defend and sustain your credits on an ongoing basis.

WITHUM R&D TAX CREDIT COMPLIMENTARY ASSESSMENT

Withum provides a no-obligation complimentary assessment with our expert team of R&D professionals whereby you can arrive at the viability of an R&D tax credit study and its potential monetary benefits through a brief discussion. The goal of this discussion is to determine quickly if there is an R&D tax credit opportunity and how Withum can assist in calculating and supporting your credit through our innovative R&D tax credit studies.