



# *SAVINGS WEEK*

**Day 1 – Foundational Tools**

by

**BIO Business Solutions®**

The largest cost savings program for  
the life sciences industry.

# BIO Business Solutions: A Membership Benefit

## What is it?

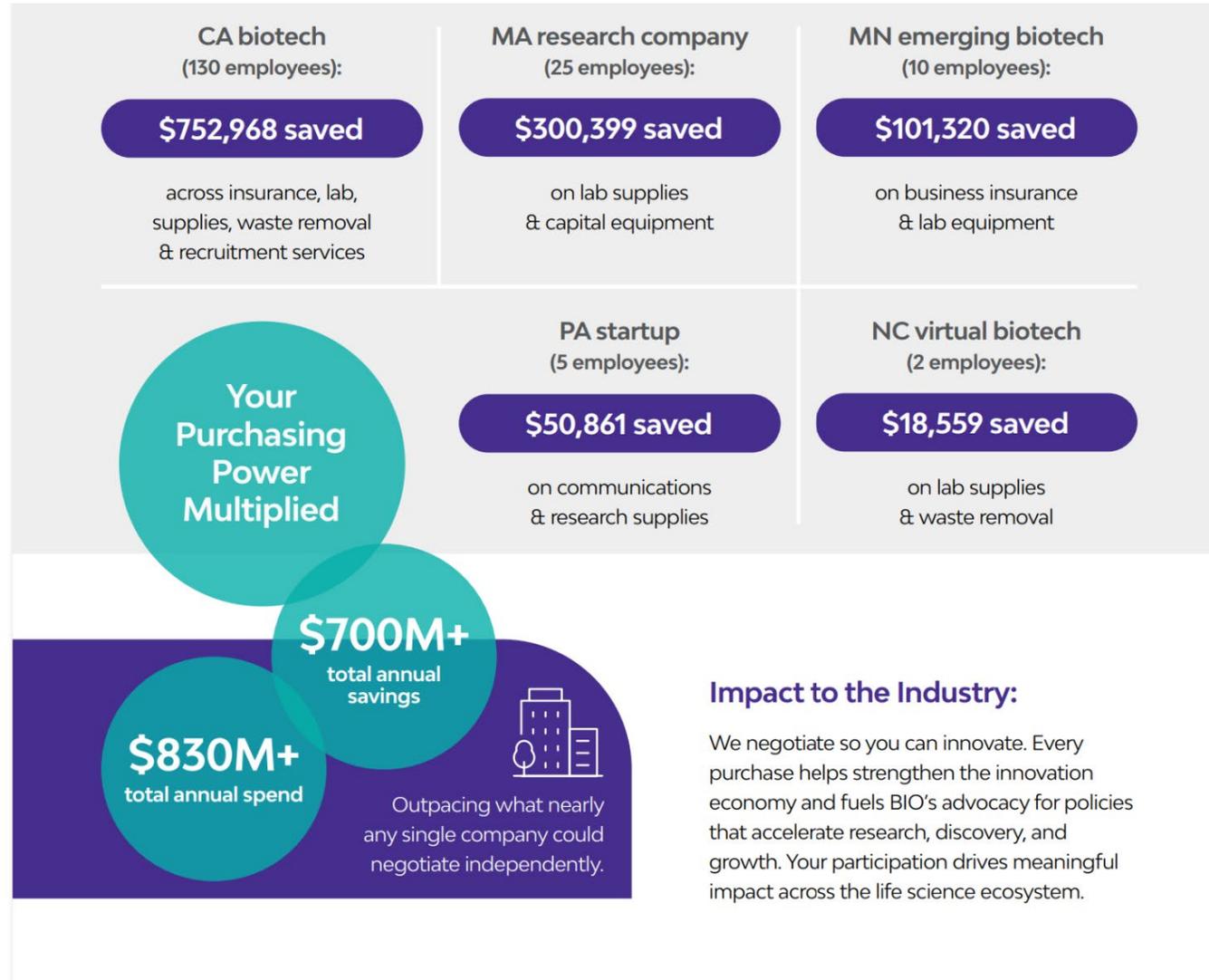
21 pre-negotiated contracts that members can use at no additional cost

BIO performs the due diligence and ensures:

- All products and services are available to all members
- Favorable rates and terms based on the leverage of all members
- Regularly updated terms that follow industry trends

LEVERAGE

# BBS Participant Savings



# Lab & Facilities



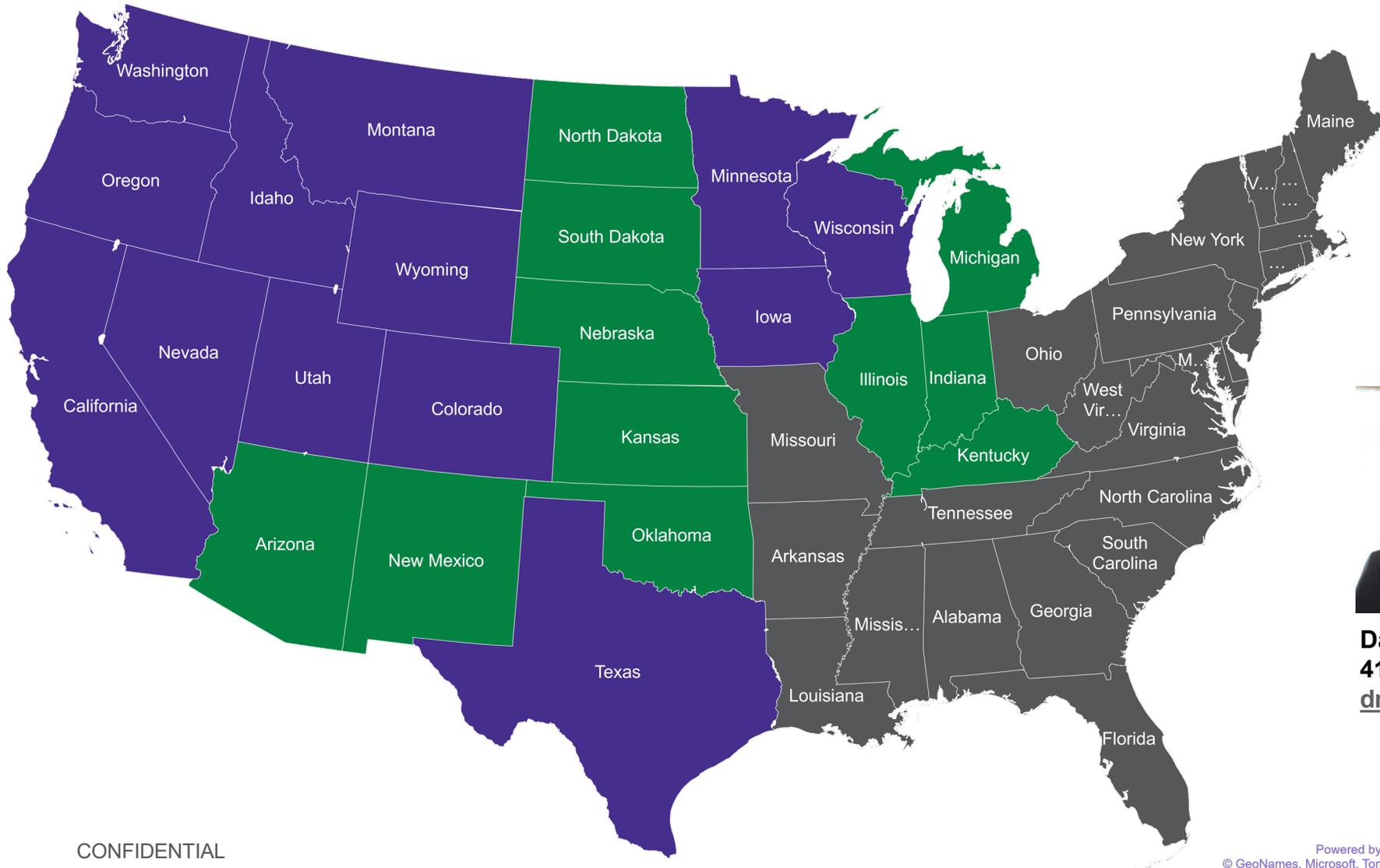
# HR & Insurance



# Corporate Services



# BIO Business Solutions® BD Team



- Neil
- Jeff
- Jim



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# Today's presenters



# ADP Run

Greg Hassan

*greg.hassan@adp.com*



# ADP & BIO: Infrastructure for Innovation

*Supporting breakthrough science with smart,  
scalable workforce solutions*



Always Designing  
for People®

# WHO'S BEHIND THE MICROSCOPE



## GREG HASSAN

Director of Franchise & Affiliations, ADP

- **Member Growth Advocate** – Over two decades experience helping member partners streamline payroll, HR and compliance so they can focus on growing their business.
- **Trusted Partner to BIO** – Works closely with some of the largest member networks in the country to deliver proven solutions that improve operations.
- **Passionate About Small Business Success** – Dedicated to making HR and payroll simple, cost-effective, and worry-free for owners, managers, and their teams

# WHY DID BIO PARTNER WITH ADP?

- Leader in HR/Payroll
- Financial stability
- Tenured quarterback
- Enhanced back-office support
- Bridge the gap Joint employer law
- Integrations with other vendors through ADP Marketplace

***Special discounted pricing  
for BIO Members!***



**#1 spot in G2's  
Best Software  
for Small  
Businesses in  
2025**



**4.5/5 Outstanding**



**2025  
TrustRadius Top  
Rated Award  
Winner**



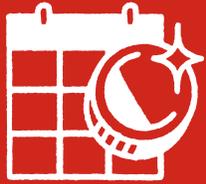
# ADP PAYROLL AND HR PACKAGES

How you manage your back-office burden can pull your focus away from reaching your long-term business goals, or it can bring you closer to achieving them.

# PREMIUM PAYROLL AND HR PACKAGES

Choose the RUN Powered by ADP® package that fits your small business best			
Features	ADP® Enhanced Payroll	ADP® Complete Payroll and HR Plus	ADP® HR Pro
Payroll: Online, Phone, Mobile	■	■	■
24/7 Customer Service	■	■	■
Tax Filing	■	■	■
Electronic Reports	■	■	■
Employee Access® (Portal)	■	■	■
New Hire Reporting	■	■	■
Payroll Delivery	■	■	■
General Ledger Interface (GLI)	■	■	■
RUN and Done® (Automatic Recurring Payroll)	■	■	■
Direct Deposit	■	■	■
Wisely® Direct Debit Card <sup>1</sup>	■	■	■
Multi-company Management	■	■	■
Multi-jurisdiction Payroll	■	■	■
W-2 and 1099 Form E-filing	■	■	■
ADPCheck™	■	■	■
Poster Compliance	■	■	■
SUI Management	■	■	■
Wage Garnishment Payment Service	■	■	■
Check Signing and Stuffing	■	■	■
Job Costing	■	■	■
HR Newsletter and Tip of the Week	■	■	■
State and Federal Resources	■	■	■
Employment Verification	■	■	■
New Hire Paperwork	■	■	■
New Hire Self-Onboarding	■	■	■
Employee Discount and Wellness Programs	■	■	■
ADP Marketplace (Digital HR Storefront)	■	■	■
Background Checks	■	■	■
ZipRecruiter®	■	■	■
HR HelpDesk (Live Support)		■	■
Employee Handbook Wizard		■	■
Salary Benchmarks		■	■
HR Toolkits		■	■
Compliance Database and Updates		■	■
Job Description Wizard		■	■
HR Forms and Documents		■	■
HR Tracking		■	■
Alerts and Notifications		■	■
Document Vault		■	■
Applicant Tracking System			■
Learning Management System			■
Business/Marketing Tools and Live Advice <sup>2</sup>			■
Upnetic Legal Services <sup>3</sup>			■

# MORE THAN JUST A PAYROLL PROVIDER



Payroll



Worker's Comp and  
Business Insurance



Health & Benefits\*



Talent



Time &  
Attendance



ADP Mobile  
App



HR Services



Retirement



Tax Credits



Outsourcing  
Options

# BEYOND PAYROLL PRODUCTS



## PAY-BY-PAY PREMIUM PAYMENT PROGRAM FOR WORKERS' COMPENSATION

- **Improve Cash Flow:** Eliminate the upfront premium deposit and spreads workers' compensation premium payments across your annual payroll cycle\*
- **Connection To ADP Payroll:** Premium payments adjust based on actual payroll data and carrier rates to minimize your over or underpayments at your year-end audit
- **Automated Payments:** Premium payments are automatically forwarded to your carrier, reducing the risk of late payments
- **Premium Reporting:** Access to detailed premium payment information at the employee, state, and class-code level to help minimize audit impact
- **Streamlined Audit:** Carriers may accept the Pay-by-Pay report during the year-end audit and approve without your involvement\*



## GROUP HEALTH THROUGH AUTOMATIC DATA PROCESSING INSURANCE AGENCY, INC. (ADPIA®)

- ADPIA provides service and support throughout the lifecycle of your group health policy.
- **Better benefits administration:** Integrate your group health insurance and ADP payroll.\*\*
  - Eliminate paper applications
  - Automate premium deductions
  - Track waiting periods
- **Dedicated relationship manager:** Benefit from a single representative to assist you every step of the way.
  - Answers policy questions and helps resolve issues
  - Helps your employees better understand the full value of their benefits
  - Annual review of your policy before renewal



## RETIREMENT SERVICES

We specialize in easy and affordable retirement plan solutions that help small businesses offer an elevated retirement experience that stands out from other providers.

- **Deep experience and knowledge:** With our vast data and technology, businesses of all sizes can design a plan that works best for them and helps employees achieve retirement readiness.
- **Personalized insights and education:** Employees can make better retirement planning decisions with personalized, guided experiences that leverage ADP's unmatched data from over 40 million+ US workers
- **Security everyone can count on:** Clients are protected with ADP's enterprise-level security that keeps their payroll and recordkeeping data in one ecosystem.

\*While premium deposits may be eliminated by most carriers, mandatory state assessment fees may be required

\*\* While Pay-by-Pay may reduce the administrative burden of the annual audit, the carrier reserves the right to perform a more in-depth audit, as outlined in your policy documents

\*\*\*To take advantage of ADP's Benefits Connector, clients must have a group health policy brokered through ADPIA and must be an ADP payroll client using RUN Powered by ADP®. Excludes Autopay clients. Certain optional features within the Benefits Connector application may require a fee.

# THANK YOU



**GREG HASSAN**

**Director of Franchise & Affiliations, ADP**

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# ADP R&D Tax Credits

Jose Arellano

*Jose.Arellano@adp.com*



# YOUR ROADMAP TO CLAIMING R&D TAX CREDITS

ADP SmartCompliance®

Tuesday March 17<sup>th</sup>, 2026



Always Designing  
for People®

# DISCLAIMER

## THIS PRESENTATION IS NOT:

- Legal advice
- The final word on today's topics
- A political opinion



Before taking any actions on the information contained in this presentation, employers should review this material with internal and/or external counsel.

# YOUR PRESENTER



## JOSE ARELLANO – ADP R&D TAX CREDITS

*Sr. Director of Channel Strategy, ADP Compliance Solutions*

Jose is a business leader at ADP with over 18 years of experience helping companies grow through strategic partnerships, tax credit incentives, and innovative workforce solutions.

In his current role as Sr. Director of Channel Strategy at ADP, he focuses on enabling partners to unlock new opportunities, drive client success, and strengthen long-term relationships.

*“I believe business is personal, and my people-first mindset has guided me in building trusted networks with CPAs, banks, brokers and business advisors across the country. My career began in sales, and over the years I’ve grown into a strategist who empowers others to succeed — whether that’s a small business owner navigating HCM, Tax Credits and compliance or a partner looking to expand their practice.”*

# BUSINESSES ARE LEAVING MONEY ON THE TABLE

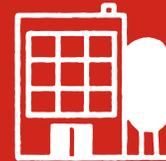


## \$20 BILLION

\$20 billion in  
**government spend** on  
R&D Tax Credits in 2022.<sup>1</sup>

<sup>1</sup>Source: Tax Expenditures, U.S. Department  
of the Treasury

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## 1/3

Only 1/3 of **eligible  
businesses claim** the R&D  
Tax Credit.<sup>2</sup>

<sup>2</sup>Source: [How to File an R&D Tax Credit](#)  
([uschamber.com](#))

# FEDERAL R&D TAX CREDIT<sup>1</sup>

The Federal R&D Tax Credit is a general business credit established in 1981 and made permanent in 2015.

Designed to **encourage US expenditures** in R&D-heavy sectors, including engineering, physical, biological, and computer sciences

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May be claimed retroactively; **businesses can generate a refund** of taxes previously paid and carry forward unused credits up to 20 years

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Additional options may be available based on the **2022 Inflation Reduction Act**

## May be monetized by offsetting:

1. Regular tax liability for all businesses; or
2. Payroll tax (employer's Social Security & Medicare portion of FICA) for businesses in their first 5 years of generating gross receipts AND gross receipts of less than \$5 million/year. (\$500K/year credit limit)

<sup>1</sup> See 26 U.S. Code Section 41 (2016); Protecting Americans from Tax Hikes Act of 2015, Consolidated Appropriations Act 2016 (P.L. 114-113), Division Q, H.R. 2029, 114th Congress (2015-2016).



# WHAT ACTIVITIES AND INDUSTRIES QUALIFY FOR R&D TAX CREDITS?

**ANY BUSINESS WITH ACTIVITIES MEETING THE REQUIREMENTS DEFINED BY TAX CODE<sup>2</sup> (AKA THE FOUR-PART TEST, ETC.) MAY QUALIFY FOR R&D CREDITS.**



## TYPICAL QUALIFYING INDUSTRIES

- Biotechnology/Pharmaceutical
- Software/Tech
- Engineering
- Manufacturing

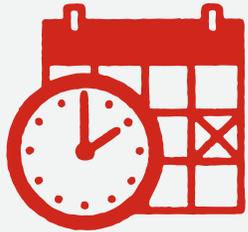
## TYPICAL QUALIFYING ACTIVITIES

- Product
- Manufacturing process
- Invention
- Technique
- Software
- Formula

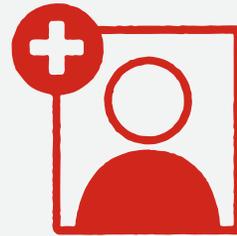
<sup>2</sup> See 26 U.S. Code Section 41 (2016); Protecting Americans from Tax Hikes Act of 2015, Consolidated Appropriations Act 2016 (P.L. 114-113), Division Q, H.R. 2029, 114th Congress (2015-2016). IRC § 41 – Qualified Research Activities

# FEDERAL R&D TAX CREDIT<sup>1</sup>

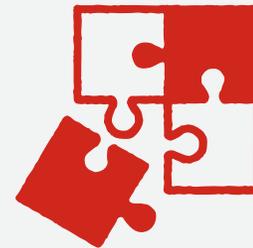
Businesses may generate a federal, dollar for dollar, tax credit typically averaging 6% — 8% of certain U.S. based costs tied to development activities, including:



**Wages** paid to employees performing, supervising, or supporting development



**Contractor expenses** paid to contractors performing, supervising, or supporting development



**Supplies** (tangible, non-capitalized raw materials) used during development



**Cloud computing hosting costs** used for software development

<sup>1</sup>See IRC section 41 (2016); Protecting Americans from Tax Hikes Act of 2015, Consolidated Appropriations Act 2016 (P.L. 114-113), Division Q, H.R. 2029, 114th Congress (2015-2016).

# INDUSTRY BREAKDOWN — LIFE SCIENCES / BIO-TECHNOLOGY

## DEVELOPMENT OR IMPROVEMENT OF:

- **Products/Formulations** – drugs, therapeutics, chemical compounds, wearables, monitoring devices, implants, prosthetics, etc.
  - **Processes** – scientific and research methods, robotics/ AI, etc.
  - **Techniques** – surgical techniques, therapy techniques, genome therapy, etc.
- 
- **Software** – bioinformatics, patient management, laboratory management, clinical data management, etc.
  - **Inventions** – patentable activities.

# INDUSTRY ILLUSTRATION — LIFE SCIENCES / BIOTECHNOLOGY

Note: Individual results may vary

## VACCINE DEVELOPMENT & IMPROVEMENTS

<b>Permitted Purpose</b>	Taxpayer is attempting to <b>develop and improve a variety of vaccines</b> and other therapeutics
<b>Technological in Nature</b>	Taxpayer used the <b>principles of physical sciences in biology</b> to develop and test various viral therapies to improved functionality of various approved drugs and eliminate or mute diseases
<b>Elimination of Uncertainty</b>	Taxpayer was uncertain, at the outset of development, as to what exact diagnosis and relevant treatments would be necessary to achieve the established functionality and performance improvement requirements
<b>Process of Experimentation</b>	Taxpayer has <b>developed and is testing various therapeutics</b> , in order to achieve the desired functionality and performance improvements

Employees	Total Annual Payroll	Time Spent on Development	Eligible Payroll
Scientists	\$700,000	80%*	\$700,000
Research Associates	\$400,000	70%	\$280,000
Direct Supervisors	\$400,000	20%	\$80,000
R&D Eligible Payroll			<b>\$960,000</b>
R&D Eligible Contract Costs (@65%)			<b>\$12,000</b>
Supplies Expense			<b>\$100,000</b>
Total Eligible Expenses			<b>\$1,072,000</b>
<i>Approximate annual R&amp;D credit</i>			<b>\$75,040</b>
<i>Approximate 4-year R&amp;D credit benefit</i>			<b>\$300,160</b>

# OBBB — IMPACT ON R&D & SECTION 174

Taxpayers may immediately expense domestic research and development (R&D) expenditures after Dec. 31, 2024

To emphasize, OBBB amended the Tax Cuts & Jobs Act (TCJA) of 2017 provisions which required taxpayers to capitalize and amortize specified **domestic R&D costs over a five-year period**

R&D activities conducted outside the U.S. **must continue to be capitalized and amortized over 15 years**

Amends the mandatory software rule so that **domestic software development costs** may be expensed immediately **but** foreign expenses must be amortized

# **TRUST AN INDUSTRY EXPERT TO CAPTURE R&D TAX CREDITS**

# ADP TAX CREDITS AND COMPLIANCE

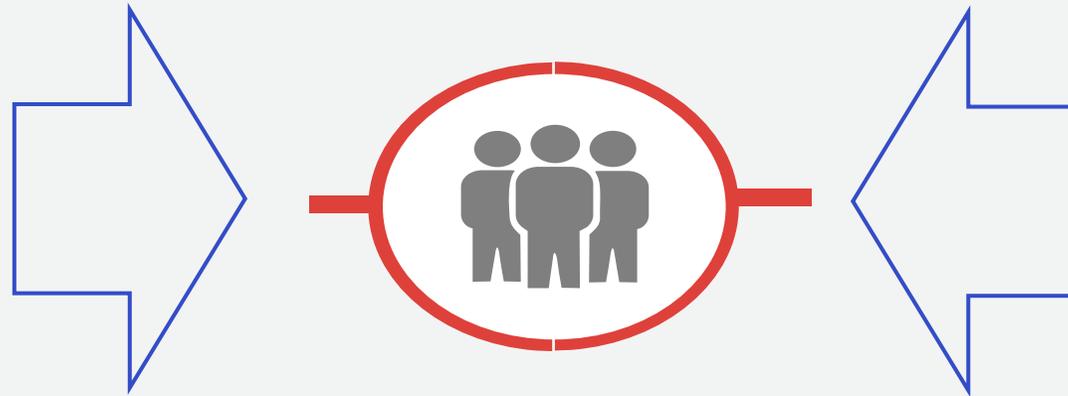
## COMPLIANCE

 45+ years of experience in tax credit processing 01

 Captured over \$6 Billion overall tax credits since 2017 02

 Dedicated In House Agency Relations staff 03

 Dedicated Government Liaison team 04



05 250 Dedicated tax credit specialists 

06 Progressive tax engine technology that supports the complexity of tax credit landscape 

07 ADP backs our tax studies with audit support 

08 Soc 1 and Soc 2 Compliant 

# ADP R&D TAX CREDITS SERVICE AND SUPPORT



## Complimentary Assessment

### Consultation includes:

1. Review tax returns, wages, supplies, expenditures, contracts to determine credit estimate.
2. Project Credit Utilization
3. Project ROI Estimation

## Full Credit Analysis

### We assign a dedicated tax specialist to conduct an intensive study to:

1. Quantitative Analysis of payroll/financial data, Predict ROI
2. Quantitative Analysis of eligible activities and utilization of credit

## Analysis and Credit Delivery

### We deliver the intensive study to Client/Accountant including:

1. Data Analysis Document
2. Final Credit Valuation
3. Detailed Guidance and Tax Credit Partnership on Filing
4. **Audit Support** on ADP R&D Tax Credits captured.

# ADP FUELS YOUR BUSINESS GROWTH

4,000+

ADP Tax Credit clients nationally<sup>1</sup>

\$6B

ADP has helped clients capture more than \$6 billion in aggregate tax credits and incentives since 2017<sup>1</sup>

## Examples<sup>1</sup> of R&D Tax Credits captured

VIDEO GAME DEVELOPER	PHARMACEUTICAL	MANUFACTURING	BIOTECHNOLOGY
<ul style="list-style-type: none"><li>▪ <b>\$1M</b> in annual revenue</li><li>▪ <b>20</b> Employees</li><li>▪ <b>\$141K</b> in credits over three years</li><li>▪ Payroll and income tax offset</li></ul>	<ul style="list-style-type: none"><li>▪ <b>\$689K</b> in credits over four years</li><li>▪ <b>665</b> Employees</li><li>▪ Income tax offset, innovation reinvestment</li></ul>	<ul style="list-style-type: none"><li>▪ <b>\$8M</b> in annual revenue</li><li>▪ <b>\$1.6M</b> in tax credits over four years</li><li>▪ <b>\$394K</b> in state tax credits</li><li>▪ <b>250</b> Employees</li><li>▪ Income tax offset</li></ul>	<ul style="list-style-type: none"><li>▪ <b>\$3M</b> in annual revenue</li><li>▪ <b>28</b> Employees</li><li>▪ <b>\$250K</b> in credits for current year</li><li>▪ Payroll withholding offset</li></ul>

<sup>1</sup> ADP Internal Data

# SHAREABLE RESOURCES

## ADP SMARTCOMPLIANCE® FOR R&D TAX CREDITS

- [R&D Tax Credits Myths Debunked](#)

## READ OUR LATEST ARTICLES

- [What's New for R&D Tax Credits](#)
- [R&D Tax Credit: What It Is and How to Claim It](#)

ADP SmartCompliance®

## SAVINGS ACHIEVED THROUGH R&D TAX CREDITS



US Pharmaceuticals is a contract manufacturing organization (CMO), private label manufacturer and distributor of over-the-counter pharmaceuticals. Their products sell through major retail pharmacies — including Walgreens, Rite-Aid and CVS — as private label brands and through institutional healthcare distributors. Unaware that the availability of R&D tax credits that could help reduce the company's tax liability was resulting in a missed opportunity to put money back into the business. Dinesh Patel, president, shares his story with ADP®.



### Business Challenge

Unaware of qualifying R&D tax credits meant money was being left on the table that could be used to reinvest back into the company.



### How ADP Helped

ADP's team of experts was able to identify qualifying tax credits retroactively for three years and will help determine eligibility moving forward.

### A history with ADP

Prior to 1999, the company was much smaller — with approximately 10 to 15 employees — and we used to handle our own payroll. But as we grew past those numbers, I turned to ADP to handle that for us. Currently we're using the RUN Powered by ADP® platform and provide our employees with health insurance, 401(k) and worker compensation through ADP, too. So, I have a very long and successful history with the products and services that ADP offers.

### Qualifying for tax credits

My experience with ADP has always been a positive one and what came next was just as welcome as it was unexpected. My new accountant contacted me and informed me that we might be eligible to qualify for existing R&D tax credits based on the type of projects we develop and work on. He did not have the time or resources to stay on top of the different types of credits available but suggested ADP could help. I was excited to learn this might be a possibility for the company and was very happy learn more about it.

Soon after, I was speaking with the ADP R&D tax credit team and they went into great detail how the tax credits — if eligible — can be beneficial to a company like mine as there was potential to save a substantial amount of money. They were very prepared and explained the various processes and resources ADP has in place that could help accurately determine our eligibility. Considering ADP's extensive experience of IRS regulations and tax knowledge, I felt confident they could identify credit opportunities — if any — available for us.

### Quick facts

**Company:**  
US Pharmaceuticals

**Industry:** Healthcare

**Owner:** Dinesh Patel

**Employees:** 46

**Locations:** 1

**Headquarters:**  
Pittsburgh, Pennsylvania

**Established:** 1981

**ADP Product:**  
RUN Powered by ADP

**Website:**  
[unipackinc.com](http://unipackinc.com)



Always Designing  
for People®

"Considering ADP's extensive experience of IRS regulations and tax knowledge, I felt confident they could identify credit opportunities — if any — available for us."

—Dinesh Patel, President,  
US Pharmaceuticals

# Brex

Gaby Levey

*[glevey@brex.com](mailto:glevey@brex.com)*



# Brex for BIO & State Life Science Association Members: Scale Smarter, Spend Better

Financial Tools Built for Life Sciences Startups



LET'S GROW TOGETHER

**The #1 financial stack for startups.**



# Quick Poll — What's Your #1 Finance Pain Point?

💡 **Question:** What's the biggest challenge your finance team faces today?

✉ **Choose one (enter in the chat):**

- 📅 Manual expense tracking and reimbursement
- 📅 Slow month-end reconciliation
- 💳 Limited card limits or control
- 📈 Lack of real-time budget visibility

# Medicinal Genomics - Scaling Finance with Brex

## About Medicinal Genomics

A biotech company using genomics to improve cannabis testing and safety.

## The Challenge

Manual expense reviews were slowing the finance team, making it difficult to scale effectively.

## The Brex Solution

- Empowered managers to review only exceptions
- Real-time spend compliance enforcement via mobile
- Integrated with NetSuite for seamless month-end close

## Results

- Saved 10+ hours/week on approvals
- Faster, more efficient month-end close
- Stronger compliance visibility

**“The increased efficiencies of Brex help us close the month faster, allowing us to scale faster.”**  
— Arlene Barbieri, Corporate Financial Controller, Medicinal Genomics

# Phase Genomics - Centralizing Spend with Brex Travel

## About Phase Genomics

A life sciences company enabling chromosome-scale genome analysis.

## The Challenge

Needed to centralize travel booking and gain visibility into distributed team spending.

## The Brex Solution

- Implemented Brex Travel for seamless global bookings
- Integrated travel, card spend, and policy enforcement
- Enabled real-time tracking and streamlined reconciliation

## Results

- Unified travel + card spend into one platform
- Reduced reconciliation time and errors
- Same or better pricing compared to external booking tools

**“We love Brex Travel because it makes it easier for everyone to book travel, and it’s connected to the card and approval flow.”** — Jason Brown, Director of Operations, Phase Genomics

# How Brex Solves Your Pain Points

## 👉 You said...

- **Manual expense tracking?** → Brex auto-generates receipts, categorizes expenses, and integrates directly with NetSuite/QuickBooks.
- **Slow reconciliation?** → Brex syncs transaction data in real time, helping teams close books 10x faster.
- **Limited spend control?** → Brex offers 40x higher card limits with customizable controls at the merchant/category level.
- **Lack of visibility?** → Brex Empower provides live budgets, mobile policy enforcement, and unified dashboards.

🌟 **Result:** Less busywork, faster decision-making, and full control of your financial stack.

# Why Member Companies Choose Brex

## Maximize Your Runway

- Earn up to 7x points on business spend
- Access \$400K+ in SaaS & services discounts
- Manage liquidity with 4.9% APY treasury accounts

## Save Time, Move Faster

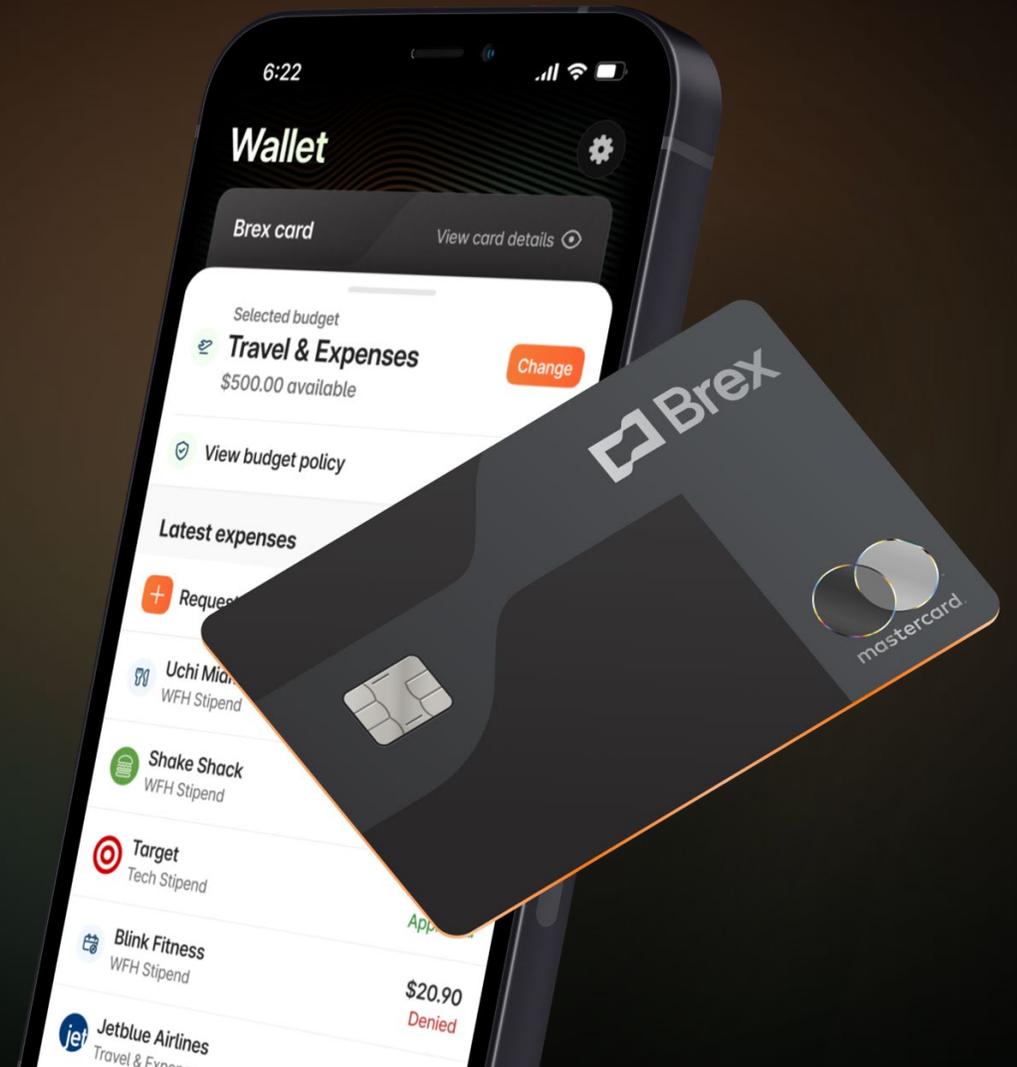
- Automate expenses and close books 10x faster
- Real-time budgets and policy alerts
- Native integrations with QuickBooks, NetSuite, and more

## Scale with Confidence

- Get up to 40x higher card limits
- Control global spend across 210+ countries
- Built-in card and travel controls for compliance

## Built for Life Sciences Startups

- Trusted by Medicinal Genomics, Phase Genomics, and 56K+ startups
- Backed by Brex support and founder community



# Brex at a Glance

## Business Account

- \$6M FDIC coverage
- 4.9% APY on cash via money market fund
- Free ACH, wires, and fast vendor payments

## Corporate Card

- 40x higher limits than legacy cards
- Category-level controls and real-time spend alerts in Slack, WhatsApp, etc
- Earn up to 7x points on rideshare, travel, restaurants

## Brex Travel

- Book flights, hotels, and cars all in-platform
- Same or better pricing vs. public sites
- 24/7 human support

## Brex Empower

- Real-time budgeting and spend visibility
- Automated expense categorization and compliance with 50+ HRIS integrations
- Auto-sync QuickBooks, NetSuite, and others to close books quickly and accurately

## Rewards & Perks

- Redeem points for cash, travel, or statement credit
- Over \$180k in startup discounts (AWS, Notion, HubSpot, Stripe)
- Billboard and PR campaigns possibilities

 **All-in-One Financial Stack, Built for Startups**

# Exclusive Offer for BIO and State Life Science Association Member Companies

## Boost Your Spending Power

- Get 50k bonus statement credit points when you deposit \$50,000
- Additional 50k bonus points after you spend \$3,000
- Up to 40x higher card limits than legacy banks

## Earn More on Every Purchase

- 7x rewards on Conference Tickets, 2x on Lab Supplies
- Redeem as statement credit, cash back, airline miles

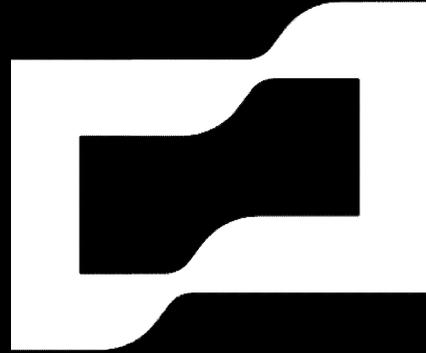
## Unlock \$180k+ in Savings

- Access exclusive Brex Perks including:
  - \$5,000 off AWS
  - \$2,500 off OpenAI
  - 30% off Hubspot
  - 6 months free of Notion Plus + unlimited AI

 Priority white-glove onboarding support, and access to investor/founder network, weekly community events and weekly industry newsletter

## March Only – Just for Members

Get an additional 25k points when you activate your account as part of BIO Savings Week.



# Questions or Ready to Get Started?

Open a (free \$0) Brex account via [brex.com/bio](https://brex.com/bio)

Reach out to me via email [glevey@brex.com](mailto:glevey@brex.com) to schedule a demo or claim your offer

# BiotechExec

Steve Joseph

*[sjoseph@biotechexec.com](mailto:sjoseph@biotechexec.com)*





BIOTECH  
**EXEC**

LIFE SCIENCE EXECUTIVES

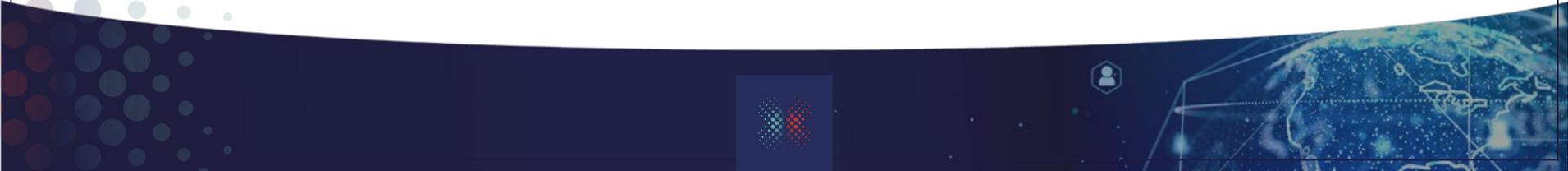
**On Demand**

# | Business Challenges

**MANY LIFE SCIENCE COMPANIES FAIL BEFORE THE SCIENCE HAS EVER HAD AN OPPORTUNITY TO PROVE ITSELF!**

## **Common reasons for business failure:**

- Lack of experienced leadership
- Difficulty raising capital
- Execution challenges
- Progress too slow for investors or the market



Q

What do life science **innovators** need to advance their company?

A

Experienced C-Suite Leadership  
- but not full time (initially)!

# Our **Novel Solution** The **IGNITE** Network



**Access** experienced life science executives  
**when you need them!**

---

Over 500 C-suite leaders **with deep industry expertise, strategic experience, and extensive investor and industry connections, and a demonstrated history of leading companies to achieve success.**





## OUR SERVICES

-  Consulting & Advisory Projects
-  Fractional & Interim CXOs
-  Conversion to Full-Time Executives
-  KOLs, SAB members, Mentors, EIRs, Board Directors

# Current & Pending Engagements

- Fractional CEO - Mitochondrial Therapeutics
- Fractional COO - Intranasal Nanoparticle Delivery
- Board Director - AI Structural Proteomics
- Board Chair - DNA-Based Drug Delivery
- Fundraising Consultant – Immunotherapy
- CMC Advisor - Precision In-Vivo Gene-Editing
- Strategic Advisor - AI Structural Proteomics
- Strategic Advisor - Patient Engagement Platform
- ARPA-H Advisor - Microgravity Drug Discovery
- FDA Advisor - NICU/PICU Monitoring

# | Our Differentiation

## Our Network

- Seasoned, life science industry C-level execs
- Large size & US-wide
- Execs come from referrals, not from searches

## Our Services

- Consulting & advisory services (from seasoned execs)
- Fractional/Part-time placement (affordable & “try before you buy”)
- Conversion to full-time placement

## Our Expertise

- “PrecisionMatch” done by industry experts
- Candidates presented in days, execs placed in weeks, not months

## Our Focus

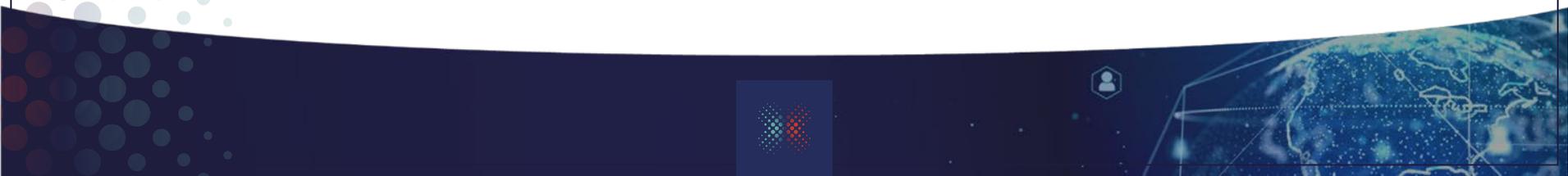
- Only life sciences – therapeutics, devices, diagnostics & digital health
- Only C-Suite – CEO, COO, CBO, CSO, CMO, CFO
- Accelerating young emerging company progress & success

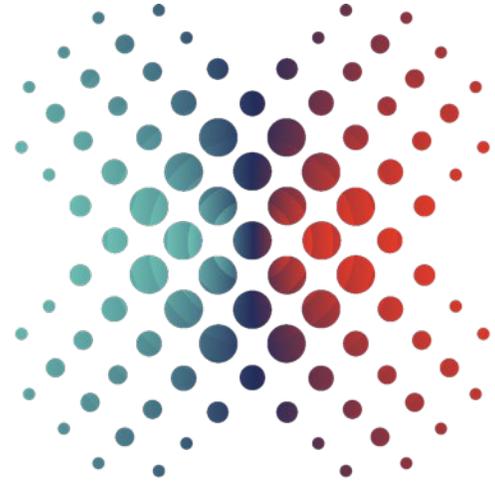
# **| BIO & State Life Science Member Benefits**

## **10% discount on BiotechExec's menu of services**

- Hourly Advisory Services
- Fractional or Contract CXO Placement
- Full-time Placement or conversion from Contract
- Board Director, SAB, and KOL Placement
- Consulting Assessments, Projects, etc.
- Precision Match – discovery, assessment and candidate matching consulting sessions
- Business Viability Assessment and Business Planning

**Complimentary first advisory session (1 - 1.5 hrs)**





BIOTECH  
EXEC

**STEVE JOSEPH**

Executive Vice President,  
Strategic Partnerships



**Call**  
(650) 333-2030



**Email**  
[sjoseph@biotechexec.com](mailto:sjoseph@biotechexec.com)

# PSC Biotech

Brandon Clough

*bclough@biotech.com*





PSC Biotech<sup>®</sup>

Contact PSC at:  
Sales@biotech.com  
PSCBio@biotech.com

 Website  
[www.biotech.com](http://www.biotech.com)  
[www.pscsoftware.com](http://www.pscsoftware.com)

# LOCATIONS



## United States

Headquarters: Los Angeles, CA

Other Office Locations: San Francisco, CA. San Diego, CA. Dallas, TX. St. Louis, MO. Chicago, IL. Indianapolis, IN. Madison, WI. Columbus, OH. Washington, D.C, York, PA. Raleigh, NC. Phoenix, AZ. Seattle, WA. Houston, Austin, Dallas, TX. Denver, CO. Orlando, FL. Puerto Rico.

### Additional States with

Technicians: Utah, Virginia, South Carolina, Connecticut, Oregon, Mississippi, Maryland, New Jersey, Michigan, Maryland

## Canada

Headquarters: Toronto, CAN



## Europe / United Kingdom

Headquarters: Ireland

Other Locations: Germany, Switzerland, Spain, Italy, France, Poland, Netherlands, Belgium, United Kingdom

## Asia

Headquarters: Singapore

Other Locations: Beijing, Shanghai, Taiwan, Japan, Malaysia, Philippines, India

## Middle East

Headquarters: Tel Aviv, Israel

Other Locations: Dubai

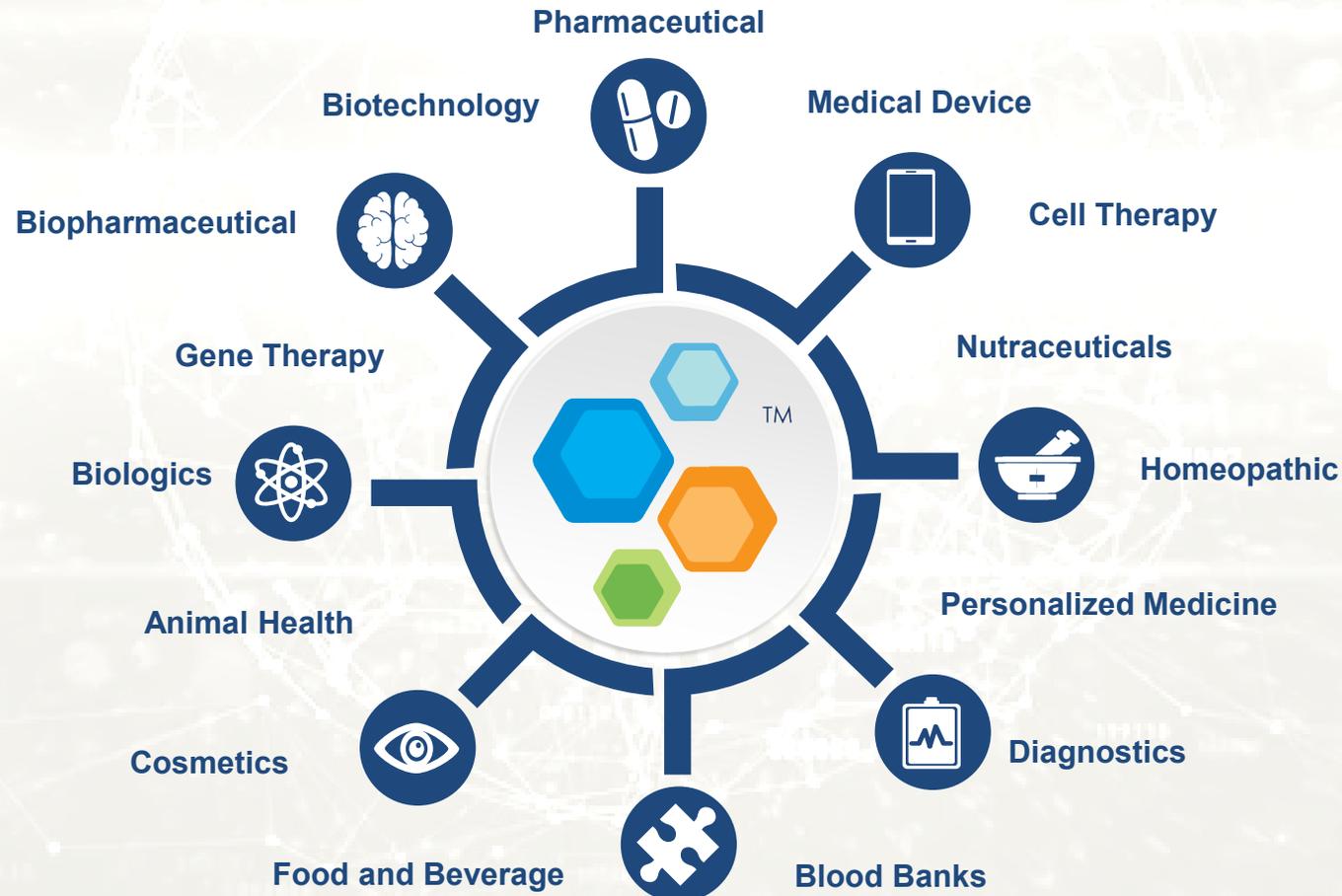
## Australia

Headquarters: Melbourne

Other Locations: Brisbane, Sydney

# INDUSTRIES WE SERVE

*We support a wide range of industries, including Pharma, Biotech, and Medical Device industries. We also support other industries that fall under Regulatory guidance, such as Cosmeceuticals, Nutraceuticals, and Compounding Pharmacies.*



# Professional Services – Small to Midsized Companies



## Quality Assurance & Compliance

- Specialized Support – Set-up and oversight
- QA Review (GLP, GMP, GCP)
- Risk Assessments
- EM Program Analysis/Creation
- Microbiology / QC Laboratory Consulting

- Supplier Auditing
- FDA / EMA Mock Inspections
- SOP's/Document/Forms
- Report Writing
- Technical Document Writing Expertise
- Deviation / CAPA

## Regulatory Support

- Regulatory Submissions
- PAI and Gap Assessment Audits
- FDA Audit Responses
- 483/Warning Letter Remediation
- Grant Writing

# Professional Services – Small / Midsized and Large Companies



## Commissioning, Qualification, & Validation

- Greenfield CQV Projects
- New Production Suite Commissioning
- Decommissioning
- Method Transfers and/or Validation
- Manufacturing and QC Lab Equipment Validation
- Facilities & Utilities Commissioning

## Computerized Systems Validation

- Enterprise System Validation
- Equipment and Instrument Software Validation
- Risk Assessment
- Data Integrity
- CSV Policies and Procedure

## Metrology Support

ISO 17025 Accredited

- Metrology plan review and preparation
- Field instrument calibration
- Chamber mapping services
- Temperature mapping, Equipment Auditing, Metrology Management, Metrology Training, Custom Instrumentation Process Assistance
- Paperless Documentation Processing (ACE)



## Equipment / System Sales and Rental

- Lives International – Thermal Mapping Equipment
- CLiMET Air Particular
- GASPOROX – Headspace Analysis and Leak Detection

### Equipment Rental & Sales

- Thermocouple systems
- Wired Validation Loggers
- Wireless Loggers
- Non-viable Particle Counters
- Temperature Wells
- Viable Particle Counters
- Steam quality test kit



# Advantages of PSC Biotech



- **Company Profile:** Experienced team with a world of expertise (~600+ employees worldwide)
- **Client Base:** Have worked with over 1000 clients in 50+ different countries
- **Proven Reputation:** Effective and efficient track record in GMP project.
- **Proven track record** for delivering turnkey CQV services
- **Local, Reliable Team:** Permanent, experienced Experts. Trained in latest Risk Based C&Q practices and digitalized validation (ValGenesis, Kneat, ACE, and others)
- Apply latest science & risk-based C&Q approaches to execute efficiently, reducing cost and allowing faster project turnaround
- **Metrology Expertise:** Full-service metrology laboratories with equipment and calibration services

# BIO & State Life Science Member Benefits

## Member Offer

10% off

- All Consulting Services



# Contact & Next Steps

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**Email: [sales@biotech.com](mailto:sales@biotech.com)**

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# PSC Software

Clark Chandler

*cchandler@biotech.com*



---



ACE<sup>®</sup>



PSCSoftware<sup>®</sup>



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# Who is PSC®



Our electronic Quality Management System (eQMS) ACE® is launched



Our turn-key eQMS ACE Essentials® is created

1996



PSC Biotech is founded to provide professional services and consulting for the life science industry

2009



Launched our revolutionary inspection management system - AuditUtopia®

2014

2020



Launched a new and innovative inspection management software - ACE Inspection®



PSC® becomes a proud member of BIO, the world's largest biotechnology advocacy association

More innovations to come!

2022



ACE® App launched on Android and iOS devices.

2024



ACE Intelligence™



ACE EBR

Release of AI Assistant – ACE Intelligence™ and ACE eBR™

2025



ACE Starter™

ACE Starter® was created to focus on what truly matters in supporting start-ups and small to medium sized businesses

# Our Client Base



Trusted by  
25,000+ users  
from over 200+  
companies  
worldwide



# ACE<sup>®</sup> Overview

- Holistic, Cloud-Based Solution
- iOS and Android Compatible
- Full Integration Capability
  - SSO, Office365, Salesforce, SAP, Oracle, ServiceNow, ADP and more
- Intuitive User Interface (UI)
- Adaptive and Highly Configurable
- Integrated Analytics and Visualizations
- FDA 21 CFR Part 11, ISO, and HIPAA Compliant
- Multilingual Support
  - English, Spanish, French, German, Italian, Japanese, Chinese (Traditional), Chinese (Simplified) & More





## BUILT-IN AI SUPPORT

Ask questions and receive real-time support



## TURN INSIGHTS INTO ACTION

Generate reports and gain insights to make informed decisions



## MANAGE DOCUMENTS EASILY

Manage and control documents effortlessly with secure features



## TRAIN TEAMS EFFECTIVELY

Automate and track employee training to maintain compliance

## FAST IMPLEMENTATION

### READY OUT-OF-THE-BOX

Complete with IQ, OQ, and PQ validated workflows and modules, along with six pre-written, industry-standard SOPs, giving users a comfortable environment to navigate and learn with ease.

## 24/7 SUPPORT

### WORKFLOWS INCLUDED:

- Course
- Curriculum
- External Training
- Trainer-Led Training
- Controlled Documents
- Document Change Control
- CAPA add-on available

# ACE Starter™

**Training Management**

Dashboard | Manage Trainings | Manage Curriculum | Manage Reviews | Manage Learners | Manage Course Settings | Training Matrix

137 Overdue | 12 Due In 1 week(s) | 0 Pending Review | 23 Learners

**Overdue Assignments**

Learner	Count
Yun-Wei Chang	14
Cindy Gross	14
Joshua Adeola	14
Justin Butera	14
Ryan Ciarcia	12
Nicholas Law	8
Leilah Rocha	8
Lisha Chai	8
Katie Chen	8
Kyle Ly	8

**Incomplete Assignments by Learner**

Learner	Count
Ryan Dellinger	14
Yun-Wei Chang	14
Cindy Gross	14
Joshua Adeola	14
Justin Butera	14
Ryan Ciarcia	14
Nicholas Law	14
Leilah Rocha	14

Format | Size | A | B | I | U | ...

Export | Import | Create Materials

**TRAINING MATERIAL**

- Assessment: Conduct a training assessment
- File: Upload training files
- Page: Provide instructions or web-based training material
- SCORM: Upload SCORM based material
- Video: Upload or link to training videos

**ORGANIZATION**

- Folder: Categorize training material into sections

**TRAINER ACTIONS**

- Intermediate Signature: Require a trainer signature on training materials

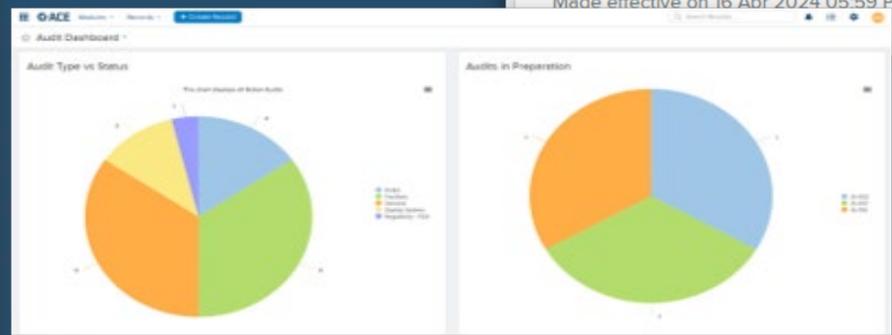
**PARTICIPANT ACTIONS**

- Attachment: Allow participants to upload a file or proof of training
- Response: Allow participants to input a response

**File Revisions**

v1.0 Effective | GH

Made effective on 16 Apr 2024 05:59 PM



All Library | Save | Clear Filter

Search Document ID & Name

- test v1.0  
BT-344-SOP  
Internal Documents > Standard Operating Procedure  
Melissa Haynes · 03/13/2024 06:42 PM
- BT-ATR-ATR-002 RS Record v1.0  
BT-071-URS  
Internal Documents > User Requirement Specification  
valuser 23 · 11/16/2023 11:46 AM
- BT-ATR-ATR-002 CS Record v1.0  
BT-070-CS  
Internal Documents > Configuration Specification  
valuser 23 · 11/16/2023 11:44 AM
- test v1.0  
BT-007-RQUAL  
Internal Documents > Requalification  
Jagger Butler · 10/11/2023 09:29 PM



### Ready-Made and Custom Prompts

Prebuilt prompts for common quality tasks help teams start fast. Tailor templates to your processes, no coding required.



### Role-Based Personas

Out-of-the-box personas, like Quality Assurance Professional, keep responses aligned to how different roles work. Customize roles as needed.



### Full Traceability of Usage

Every prompt, response, and AI action is logged in ACE, tied to a user, and available for metrics and attribution.



### Permission-Based for Data Integrity

AI access privileges can be set per record type, or fine-tuned to specific records, protecting confidentiality and maintaining security within the system.

# BIO & State Life Science Member Benefits

## Member Offer

### **ACE Starter™**

\$5k/year for 5 users and free CAPA add-on

### **ACE Essentials®**

15% discount on licensing, up to 35% discount on services

### **ACE Enterprise®**

15% discount on licensing, up to 35% discount on configuration/validation/consulting services



## Exclusive BIO Savings Week Offer

# ACE Starter = FREE for 3 or fewer Users

(once at 5 users or more \$5K/year will start)



Thank you!



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Cell: +1 909-220-4193



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