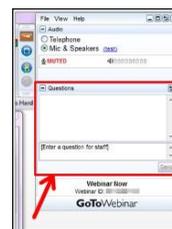




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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019



Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework, careful planning of timing and projected costs to secure needed regulatory approvals is essential.

What You Will Learn

- Working with gene editing technology poses unique intellectual property and regulatory challenges, from the R&D discovery through post-launch phases of the product development lifecycle
- The current regulatory framework is product specific, currently morphing and complicated by global trade issues
- To be most effective, intellectual property strategy needs to be tied to business goals, and focused on developing offensive and defensive positions beyond the traditional "is it patentable" lens

EXPERTS



Cassie Edgar
McKee, Voorhees &
Sease



Jonathan Kennedy
McKee, Voorhees &
Sease

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<https://www.acs.org/content/acs/en/acs-webinars/business-entrepreneurship/gene-editing.html>

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Upcoming ACS Webinar

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Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research

Drug Design and Delivery Series | September 19, 2019



Over the past 50 years, crop protection has evolved from using pesticides in high use rate to applying safer, selective, and more efficacious products, which share many of the features of modern drugs. Resistance development and environmental concerns are key drivers in the search for new, improved agrochemicals, which are currently discovered and optimized following a complex and demanding path similar to that followed in drug discovery.

Join Fides Benfatti of Syngenta Crop Protection during this free interactive broadcast as she demonstrates through various case studies much like Drug Discovery, crop protection research is a daunting challenge that has to be faced with world-class science where both industries can gain valuable insight from each other.

What You Will Learn

- What are the challenges to identify safe, selective, and efficacious agrochemicals
- How these challenges are addressed, revealed through case studies
- Similarities and differences between crop protection and pharmaceutical research

EXPERTS



Fides Benfatti
Syngenta Crop
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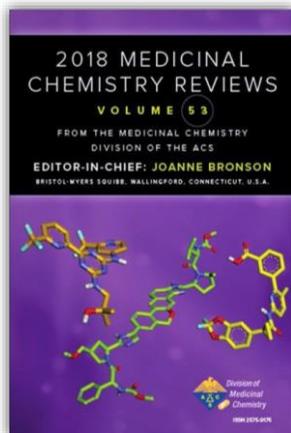
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<p>Drug Discovery Series #1 - Current Drug Discovery and Development Process 000 #11 Watch the overview of the drug discovery and development process to learn the stages and challenges in a new drug.</p> <p>Primer in Drug Target Classes 000 #12 Learn in an hour on the top 10 drug target classes and the difference between small molecule and biopharmaceutical targets.</p> <p>Key Concepts in Identifying Drug Targets 000 #13 Discover how drug targets in a new concept explore the Rule of Five, and what you learn from the lead-like guide to success.</p> <p>Lead Optimization - Building Efficiency & Safety 000 #14 Learn strategies on how to effectively optimize small molecule hits and rapidly assess your findings.</p> <p>Tips for Hit, HT and Starting Point Clinical Trials 000 #15 What do you need to know when starting the medicinal drug development to the United States Food and Drug Administration?</p> <p>The Role of Chemistry in Clinical Trials: The Big Picture & 000 #16 Learn how the process of drug development impact decisions in the discovery process.</p> <p>Pharmacokinetics and AD of Spices in Drug Development 000 #17 Review the basic principles of Pharmacokinetics and AD of spices and how they can be used to reduce the risk in determining health insurance coverage of drug products.</p> <p>Focus of Drug Discovery: Challenges, Risks and Rewards 000 #18 Explore how the risks and challenges will be taken on the future and the way you can be prepared of future marketing strategies.</p>	<p>Designing Better Drug Candidates 000 #19 Learn how to design better drugs for use in drug development using the 3D-Plus Law.</p> <p>Strategies to Improve Solubility of Drug Candidates 000 #20 Learn a number of different strategies for improving drug solubility through molecular modification.</p> <p>Program to Assess Drug Target Selection 000 #21 Find out the right drug target in your program by using the right drug target in your program by using the right drug target in your program.</p> <p>Screening Strategies 000 #22 Learn the pros and cons of different screening strategies.</p> <p>Assessing PK/PD (pharmacokinetics/pharmacodynamics) Models 000 #23 Learn how to assess the value of PK/PD models in drug development.</p> <p>Assessing QED (Quality of Drug Development) (QED) 000 #24 Learn how to assess the value of QED models in drug development.</p> <p>Key Concepts in Drug Discovery 000 #25 Learn how to assess the value of drug discovery models in drug development.</p> <p>Challenges and Trends in Drug Discovery 000 #26 Learn how to assess the value of drug discovery models in drug development.</p> <p>Delivery Systems to Support Drug Development in Preclinical Studies 000 #27 Learn how to assess the value of drug discovery models in drug development.</p> <p>Pharmaceutical Considerations in Drug Design and Development 000 #28 Learn how to assess the value of drug discovery models in drug development.</p> <p>Principles of Drug Discovery 000 #29 Learn how to assess the value of drug discovery models in drug development.</p>	<p>I - Time The Fourth Dimension in Drug Discovery</p> <p>The Importance of Drug Target Metrics in Drug Design Robert Galambos - Boston, MA Dan Epstein - Carlsbad, California</p> <p>Long Acting Injectable Medications: Strategies and Molecular Considerations John Raftery - Alameda Andrew Blair - Merck</p> <p>Modified Release Formulations for Solubility Starved Compounds Mangesh Rao - Merck John Morrison - BMS</p> <p>The Molecular Control of Tumor Suppressor Joe Barish - Johnson Ray Targatz - Merck Molly Schindl - Tech Coast Angels</p> <p>II - Beyond Traditional Small Molecules</p> <p>Design of Deliverable Macromolecules Boris Lelander - U.S. San Diego Nicholas Meinert - BMS</p> <p>Designing Big and Thinking Small: Applying Medicinal Chemistry Strategies to Antibody Drug Conjugates L. Stephen Topp - Pfizer Pavel Berner - Sanofi-Sintaris</p> <p>Novel Acids Therapeutics: Making Sense of Antibiotic Design Pavel Berner - Sanofi-Sintaris Richard Chan - BMS</p> <p>Cryobiography as a Drug Design and Delivery Tool: Clinical Trials Robert Anderson - Cytex Pharmaceuticals Andrew Burdick - Merck</p> <p>III - Pharmacology Revisited</p> <p>Designing with Biomimetic Drug Interactions in Drug Discovery: Can We Predict Toxicities of Drug Candidates that Don't React? Dariusz Daniluk - Pfizer Patrick Peier - GlaxoSmithKline Rational Design of Small Molecules Targeting BTK Walt Deryn - Sanofi Andrew Carter - University of Michigan</p> <p>Cell Penetrating Peptides to Improve Cellular Drug Uptake Debra Lee - The Ohio State University Scott Hahn - Bristol-Myers Squibb</p>	<p>I - Fighting Cancer</p> <p>Fighting Cancer-Targeting OX40 Inhibitors with Kinase Inhibitors Timothy J. Heffron - Genentech Mark Wotman - Bristol-Myers Squibb</p> <p>Fighting Cancer - Epigenetic Targets for Oncology Suzanne Conway - Celgene Sharan Baghel - AstraZeneca</p> <p>Fighting Cancer - Allosensory and Targeting Cancer Cell Metabolism Sofian Ghossein - Agios Scott Schreiber - Novartis</p> <p>Special Breakfast</p> <p>Cyclic Peptides: Discovery of CTR Modulators Naveen Chandra - Vertex Noel Newman - Bristol-Myers Squibb</p> <p>II - Anti-Infectives</p> <p>Anti-Infectives: Rational Approaches to the Design and Optimization Justin Salvo - Brown University Clayton Aldrich - University of Minnesota</p> <p>Tuberculosis: An Introduction to Medicinal Chemistry Carl Hamner - Wall Central Medicine Christopher Boyce - Merck</p> <p>Special Breakfast</p> <p>Spinal Muscular Atrophy Kevin Metzger - Harvard Medical School Aayan Neerajani - ACS Publications</p> <p>III - Immunology</p> <p>Parasitic Treatments and Novel Approaches Frank Tarace - AstraZeneca John Morrison - Bristol-Myers Squibb</p> <p>Lupus: Treatment and Novel Approaches Laurenza Mariani - Bristol-Myers Squibb Maya Juchacz - Bristol-Myers Squibb</p>	<p>I - A New Strategy in Drug Discovery: Proteasome-Induced Protein Degradation Jan Chachar - Benevolence Aparajita Singh - Bristol-Myers Squibb</p> <p>II - Women in Drug Discovery and Development: How to Succeed as a Female in Academia and Industry Annette Bai - AstraZeneca Dorina Murray - University of Pittsburgh Britta Anand - Bristol-Myers Squibb Nutan Zaveri - AstraZeneca</p> <p>III - A Nanomedicine Overview for mRNA Delivery: Innovative Methods Using Lipid Nanoparticles Marina Yarnal - AstraZeneca Dennis Liang - Genentech</p> <p>IV - Nanomedicine for Fighting Antibiotic-Resistant Bacteria Vincent Roberts - University of Massachusetts at Amherst Christopher England - American Chemical Society</p> <p>May - Advanced Nano-Delivery Systems: Facilitating Tumor Delivery and Mitigating Resistance Mehmet Arslan - Harvard University Venkat Krothammurthy - AstraZeneca</p> <p>June - Pathways and Progress of Central Nervous System Drug Discovery Vedant Ghoshal - Yale University Nicholas Meinert - Bristol-Myers Squibb</p> <p>July - How to Optimize Central Nervous System Therapeutics: Med Chem Strategies, Toxics, and Bioassays Craig Lindley - Vanderbilt Center for Neuroscience Drug Discovery Amy Hesterman - International Research Program, Ltd.</p> <p>Sept - A Novel Strategy for the Treatment of Chronic Pain: Antagonizing P2X2 with a Monoclonal Antibody Neil Thompson - AstraZeneca Nutan Zaveri - AstraZeneca</p> <p>Oct - How to Develop Human Cell-Free Protein Production and Automated Mathematical Modeling Elizabeth De Lange - Leibniz Academic Center for Drug Research Alexander Trötschel - University of North Carolina</p> <p>Nov - Human Endosomes: An Ideal Vehicle for Delivery of Therapeutic Proteins Celia Gellera - Genentech Hadi Vokori - University of Gothenburg Alexander Kapustin - AstraZeneca</p>

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Jan 31 **How to Succeed in Drug Discovery: Insight from Medicinal Chemists** (1.5 hrs.)
John Lowe III - JLI3 Pharm
Mark Murcko - Relay Therapeutics
Ann Weber - Kallyope
William Greenlee - MedChem Discovery Consulting



Feb 28 **Cosolvent Molecular Dynamics: Mapping Protein Surfaces to Discover Allosteric Sites**
Heather Carlson - University of Michigan
Rommie Amaro - UC San Diego



Mar 28 **Women at the Interface of Computational Chemistry and Drug Discovery** (1.5 hrs)
Zoe Cournia - Biomedical Research Foundation and *JCIM*
Kate Holloway - Gfree Bio
Yvonne C. Martin - Previously of Abbott Laboratories
Shana Posy - Bristol-Myers Squibb



Apr 18 **Effective Exploration of Chemical Space in Hit-Finding**
Hanneke Jansen - Novartis Institutes for BioMedical Research
Zoe Cournia - Biomedical Research Foundation and *JCIM*



May 30 **Widening the Therapeutic Window: Kinetic Selectivity and Target Vulnerability**
Peter Tonge - Stony Brook University and *ACS Infectious Diseases*
Stewart Fisher - C4 Therapeutics



Jun 27 **Precision Control of CRISPR-Cas9**
Amit Choudhary - Broad Institute of Harvard and MIT
Venkat Krishnamurthy - AstraZeneca



Aug 8 **Transformation of Recombinant Cells to FDA Approved Products: Clinical Development to Marketplace (New Date)**
Rodney Ho - University of Washington
Venkat Krishnamurthy - AstraZeneca



Aug 22 **The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models**
Bart DeCorte - MercachemSyncom
Allen Reitz - Fox Chase Chemical Diversity Center



Sep 19 **Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research**
Fides Benfatti - Syngenta

Oct 24 **Treating Diabetes: Designing the Once-Weekly and Oral GLP-1 Semaglutide**
Jesper Lau - Novo Nordisk A/S

Nov 28 **Prodrugs**
Jarkko Rautio - University of Eastern Finland

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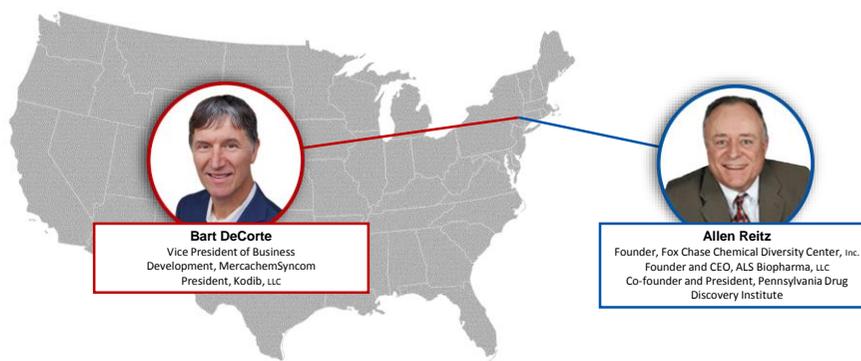
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The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models



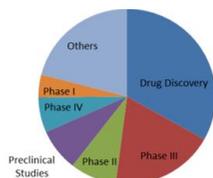
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Overview



- Outsourcing by the numbers
- Evolution of the pharma R&D model
- Outsourcing models
- Pros and cons of different models
- Factors to consider when choosing a CRO



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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



My organization...

- Is a client that partners with CROs to execute its drug discovery programs
- Is a CRO that provides specialized services (chemistry, biology, etc.)
- Is a CRO that provides integrated services (combination of chemistry, biology, eADME and in vivo pharmacology services)
- Question not applicable to me

** If your answer differs greatly from the choices above tell us in the chat!*

Outsourcing by the Numbers



The **global healthcare contract research organization market** size is expected to reach **USD 54.7 billion by 2025** with an expected CAGR of 6.6% ⁽¹⁾



The **global drug discovery outsourcing market** was expected to reach **\$22.69 bn in 2018**, dominated by the chemistry services segment. Expected to grow at a CAGR of 11.7% between 2018 and 2023 ⁽²⁾



The **CRO market** is expected to reach **\$44.4 billion in 2021** and is forecasted to grow 12% year-on-year through 2021 ⁽³⁾



Over **80% of biopharma** respondents report **increased alliance activity** compared to 5 years ago ⁽⁴⁾



⁽¹⁾ <https://www.grandviewresearch.com/press-release/global-healthcare-cro-market>

⁽²⁾ <https://www.visiongain.com/report/global-drug-discovery-outsourcing-market-forecast-to-2028/>

⁽³⁾ https://www.outsourcing-pharma.com/Article/2018/05/03/CRO-market-to-reach-44.4bn-by-2021?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright

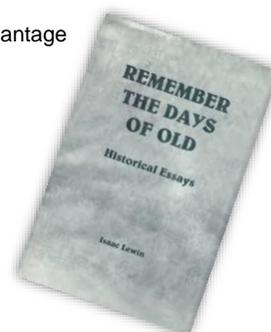
⁽⁴⁾ <https://www.vantagepartners.com/insights/the-perils-and-promise-of-strategic-partnering-with-cros/>



The Days of Old – Dominated by Big Pharma

Drug Discovery Model:

- Long-term commitment to specific therapeutic/disease areas
- Internal scientists are considered world-leading experts – key to competitive advantage
- ‘Not invented here syndrome’
- Occasional relationships with top academic institutions
 - No strings attached
 - Little or no alignment with internal priorities
 - Publications



Execution:

All aspects of the drug discovery process are executed internally

- Chemistry
- Vitro biology
- Vivo pharmacology
- Toxicology
- Process R&D
- Clinical Development



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The Turbulent 2000's

Major transformation of how pharma executes drug discovery:

- Significant head count reductions in internal drug discovery and development
- Search for cheaper ways to execute science



Drivers:

- Increased cost of R&D
- Patent expirations
- Unrealized benefits from consolidations
- Increased regulatory pressures
- Reimbursement



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Need for More Cost-Effective Execution



First phase: Clinical activities

- Need for global clinical research network

Second phase: Chemical development activities

- Sourcing of building blocks
- Assembly of intermediates (non-GMP)
- GMP production

Third phase: Drug discovery activities

- Dramatic shift of resources to lower cost countries to perform 'routine science'
- Capital efficiency: fixed costs become variable costs
- Capital flexibility: resources and spending can be adjusted rapidly



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Increased Complexity of Drug Discovery

Chemistry:

- Fragments
- *In silico* libraries
- Flow chemistry
- Chiral technologies
- DNA-encoded libraries
- PROTACS

Biophysical techniques:

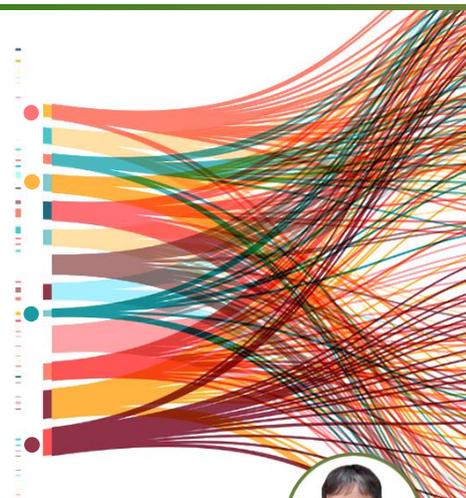
- X-ray
- Cryo EM
- NMR
- Etc.

Biology:

- Molecular targets
- Protein production
- Screening platforms
- High content screens
- Omics

Big Data and AI:

- Novel targets
- Coupling of gene expression data with clinical data
- Etc.



No organization has the resources to bring all the expertise and tools in-house.



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Relocation / Redistribution of Risk

- Recruit external investment in drug discovery process
- Let biotech companies and venture capital take on most of the risk
- Large pharma companies more and more become drug development and marketing machines
- Some of the CROs now are major investors in venture funds



In the past 20 years, the industry went from

not invented here syndrome...



to



... the world is our laboratory



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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



To what extent does your organization rely on CRO partnerships?

- We do not work with CROs to execute our drug discovery programs
- We use CROs for less than 1/3 of our drug discovery programs
- We use CROs for 1/3 to 2/3 of our drug discovery programs
- We use CROs for more than 2/3 of our drug discovery programs
- My organization is a provider of services

** If your answer differs greatly from the choices above tell us in the chat!*

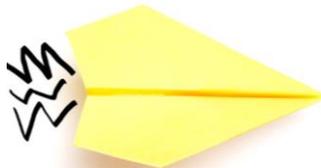
Outsourcing Models



Tactical Outsourcing Model



- Typically short-term in nature
- Focused more on delivering a specific service as opposed to a value-added service
- Convenient way to expand capacity when internal resources are limited
- Often motivated by need to manage peak work volume and to accelerate completion of projects more quickly



Often based on **fee-for-service (FFS)** arrangements

Risk lies mostly with CRO



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Strategic Outsourcing Model



- Often based on blend of in-house and external resources
- Expectation of added value contributions
- Prioritizes longer term collaborative partnerships over short term project tasks
- Goal: establish reliable external partnerships



Often based on **Full Time Equivalent (FTE)** arrangements
Shared risk

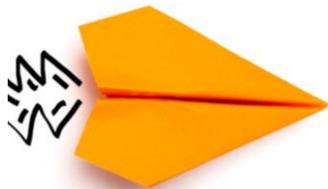


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Insourcing Model



- Less common
- Mostly limited to large pharma organizations
- Frequently driven by excess real estate



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Risk Sharing Partnerships

- Project can originate at CRO or at pharma organization
- Milestone and possibly royalty payments
- IP can be shared or fully transferred to pharma organization
- CRO may agree to lower FTE (full time equivalent) rate or offer in-kind services



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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

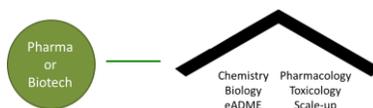
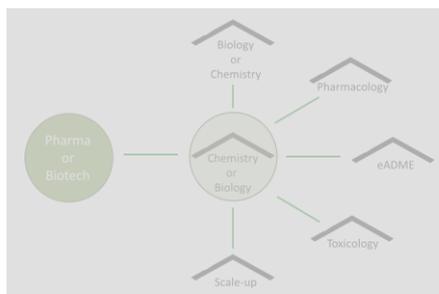
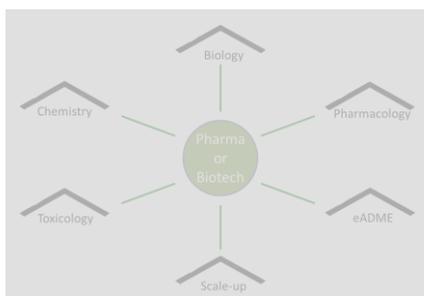


My organization's relationships with CROs are mostly based on:

- FFS (fee-for-service) based agreements
- FTE (full time equivalent) based agreements
- A mixture of both FFS and FTE agreements
- Risk sharing agreements
- Question not applicable to me

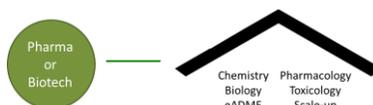
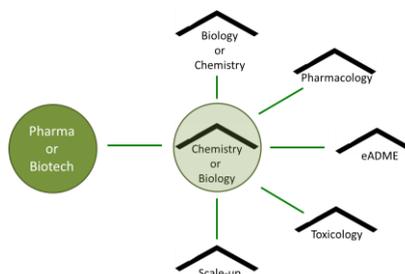
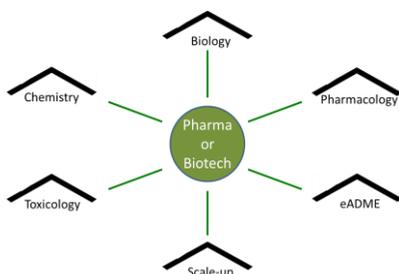
** If your answer differs greatly from the choices above tell us in the chat!*

Decentralized vs. Integrated Partnerships



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Decentralized vs. Integrated Partnerships



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Factors to Consider when Choosing a CRO

- Cost
- IP considerations
- Academic/industrial
- Data sharing and data integrity
- Safety and personnel policies
- Problem Solving skills
- Communication
- Turnover



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Cost

- FTE rates vs. what is my objective
- Compare apples to apples

Ask the *right* questions



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IP Considerations

- What part of the work do you outsource?
- Cultural differences
- Transfer of information into patent filings
- Turnover



Trust is as important as a CDA



37

Data Sharing and Data Integrity

- What part of the work do you outsource?
- Access to raw data
- Turnover



*Make sure the data are **complete**, **consistent** and **accurate** throughout the project and the data lifecycle*

<https://www.pharmaceutical-technology.com/compliance-consulting-and-training/data-integrity-pharma-nsf>



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Academic vs. Industrial Collaborations

Academic

- At the forefront of science
- Lower cost
- Level of understanding of industry mindset
- Speed of execution
- Next steps?
- IP



Industrial

- Therapeutic area expertise
- Higher cost
- Next steps?
- IP



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Turnover and Problem Solving Skills



Turnover

- Stability of the workforce
- Access to legacy information
- Protection of intellectual property

Problem Solving Skills

- Level of training of workforce
- Understanding of areas of expertise
- Firewall model
- Open access to collective knowledge base



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Communication

- Written (ppt, written reports)
- Oral (TCs and project meetings)
- Cultural (east/west – north/south)
- Time zones
- Face-to-face meetings



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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



In the next 3 to 5 years, my organization will...

- Increase its reliance on CROs
- Decrease its reliance on CROs
- Keep its reliance on CROs unchanged
- Question not applicable to me

** If your answer differs greatly from the choices above tell us in the chat!*

In Summary

- The past 20 years have seen a dramatic transformation of how pharma and biotech execute their science
- This trend is irreversible and CROs are here to stay
- Initial driver of outsourcing was cost

Today's drivers are multiple and include:

- Access to expertise and technologies
- Intellectual input
- High quality execution
- Risk sharing



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Choosing the right partner can mean



the difference between success and failure!



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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019



Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework,

careful planning of timing and projected costs to secure needed regulatory approvals is essential.

What You Will Learn

- Working with gene editing technology poses unique intellectual property and regulatory challenges, from the R&D discovery through post-launch phases of the product development lifecycle
- The current regulatory framework is product specific, currently morphing and complicated by global trade issues
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EXPERTS



Cassie Edgar
McKee, Voorhees &
Sease



Jonathan Kennedy
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Upcoming ACS Webinar

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Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research

Drug Design and Delivery Series | September 19, 2019



Over the past 50 years, crop protection has evolved from using pesticides in high use rate to applying safer, selective, and more efficacious products, which share many of the features of modern drugs. Resistance development and environmental concerns are key drivers in the search for new, improved agrochemicals, which are currently discovered and optimized following a complex and demanding path similar to that followed in drug discovery.

Join Fides Benfatti of Syngenta Crop Protection during this free interactive broadcast as she demonstrates through various case studies much like Drug Discovery, crop protection research is a daunting challenge that has to be faced with world-class science where both industries can gain valuable insight from each other.

What You Will Learn

- What are the challenges to identify safe, selective, and efficacious agrochemicals
- How these challenges are addressed, revealed through case studies
- Similarities and differences between crop protection and pharmaceutical research

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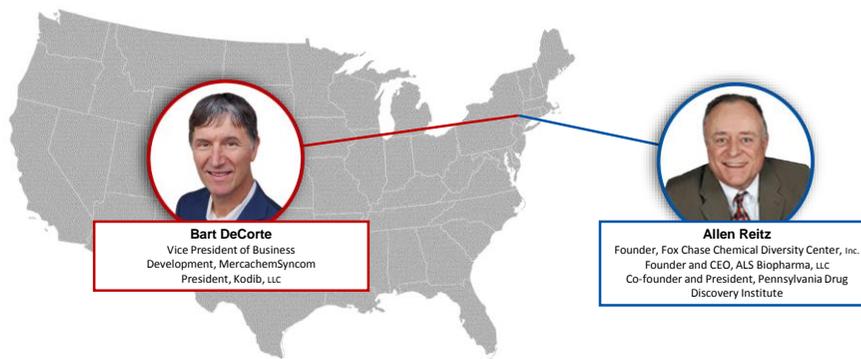
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The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models



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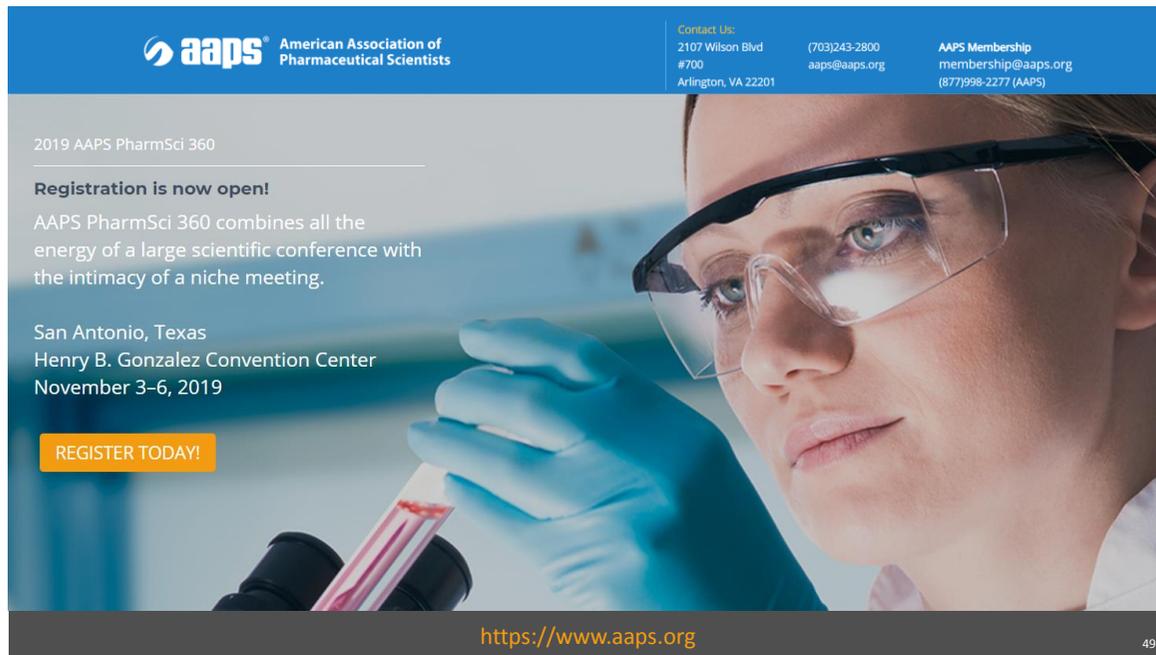
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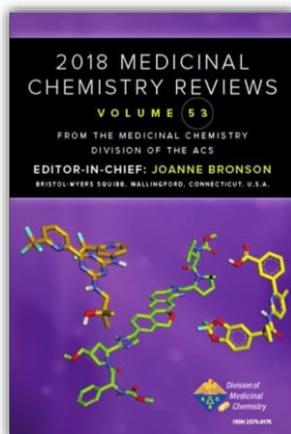
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Upcoming ACS Webinar!

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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019



Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework, careful planning of timing and projected costs to secure needed regulatory approvals is essential.

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