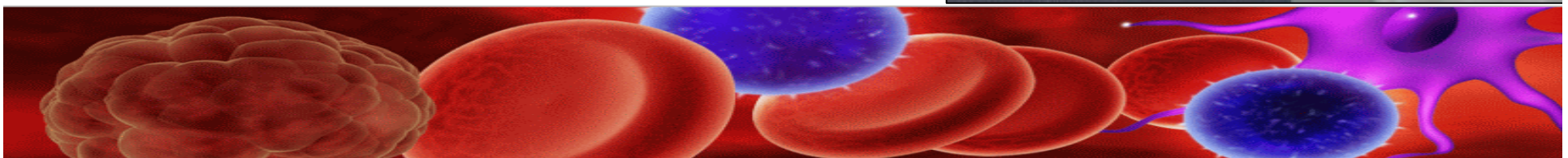


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Is outsourcing right for me?

R. Lee Buckle, BEd, LLB
Progenitor Cell Therapy, LLC



Little room for error... no one-size-fits all

- § **What are the primary challenges?**
- § **How to decide “make vs buy”?**
- § **How to successfully outsource?**

Challenges of Cell-based Product Development and Commercialization



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Commercialization Infrastructure



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Required Expertise

Multifaceted, cell-therapy-specific talent set with experience/expertise in

- Cell product development & characterization
- Construction/validation/operation of facilities
- Regulatory Affairs
- Science
- Clinical trial
- Product & process development
- Project management
- Corporate & financial executive management (prereq)

Cell-based Product Challenges

Commercializing great science requires

- Economics, logistics & feasibility of manufacture
- Product characterization, potency & comparability
- Clinical trial design, execution & duration
- Intellectual property – freedom to operate

In the context of

- ü Evolving regulatory frameworks
- ü Not many people who know how to do it
- ü Restrained financing environment

Cell Therapy Commercialization

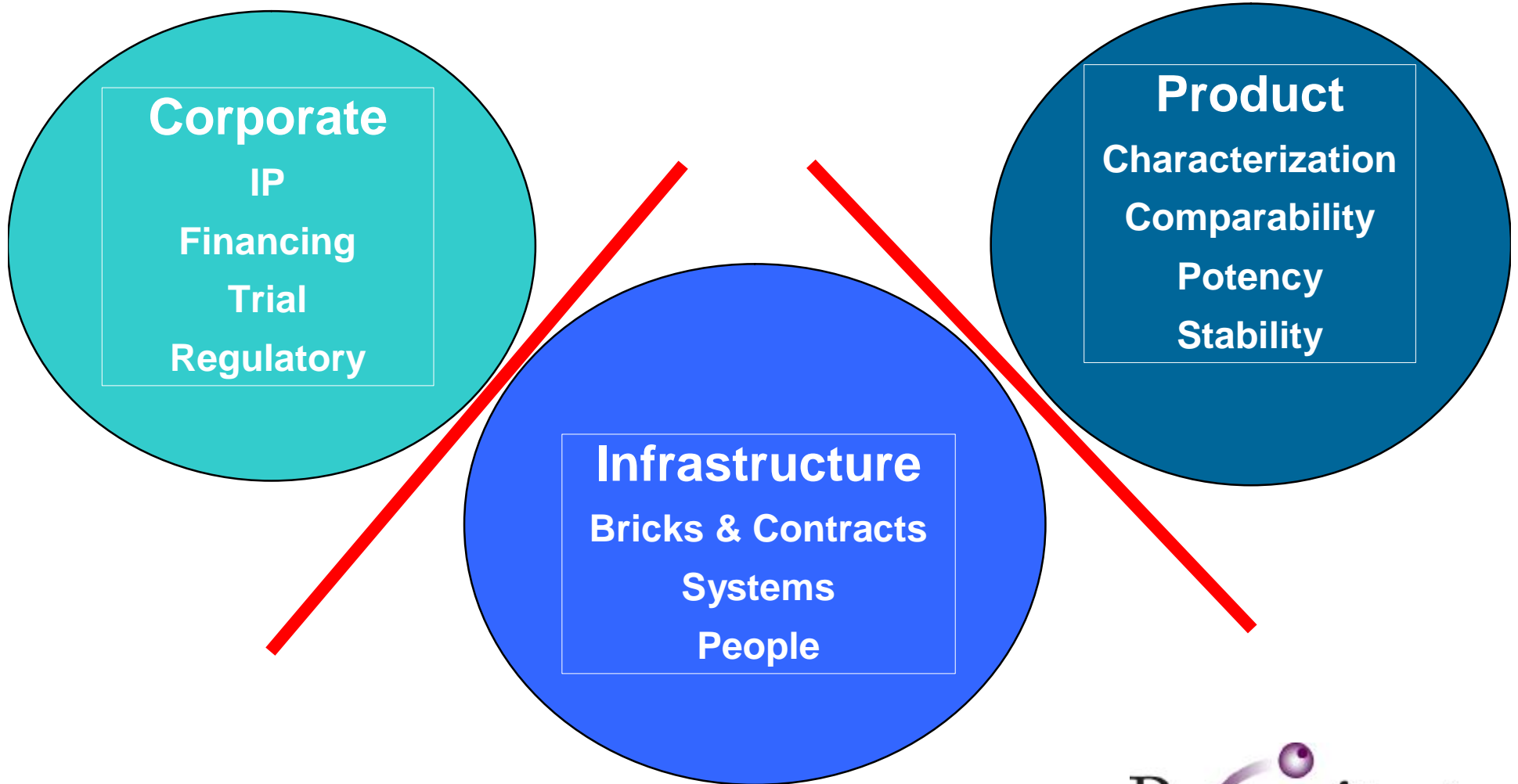
Corporate
IP
Financing
Trial
Regulatory

Infrastructure
Bricks & Contracts
Systems
People

Product
Characterization
Comparability
Potency
Stability

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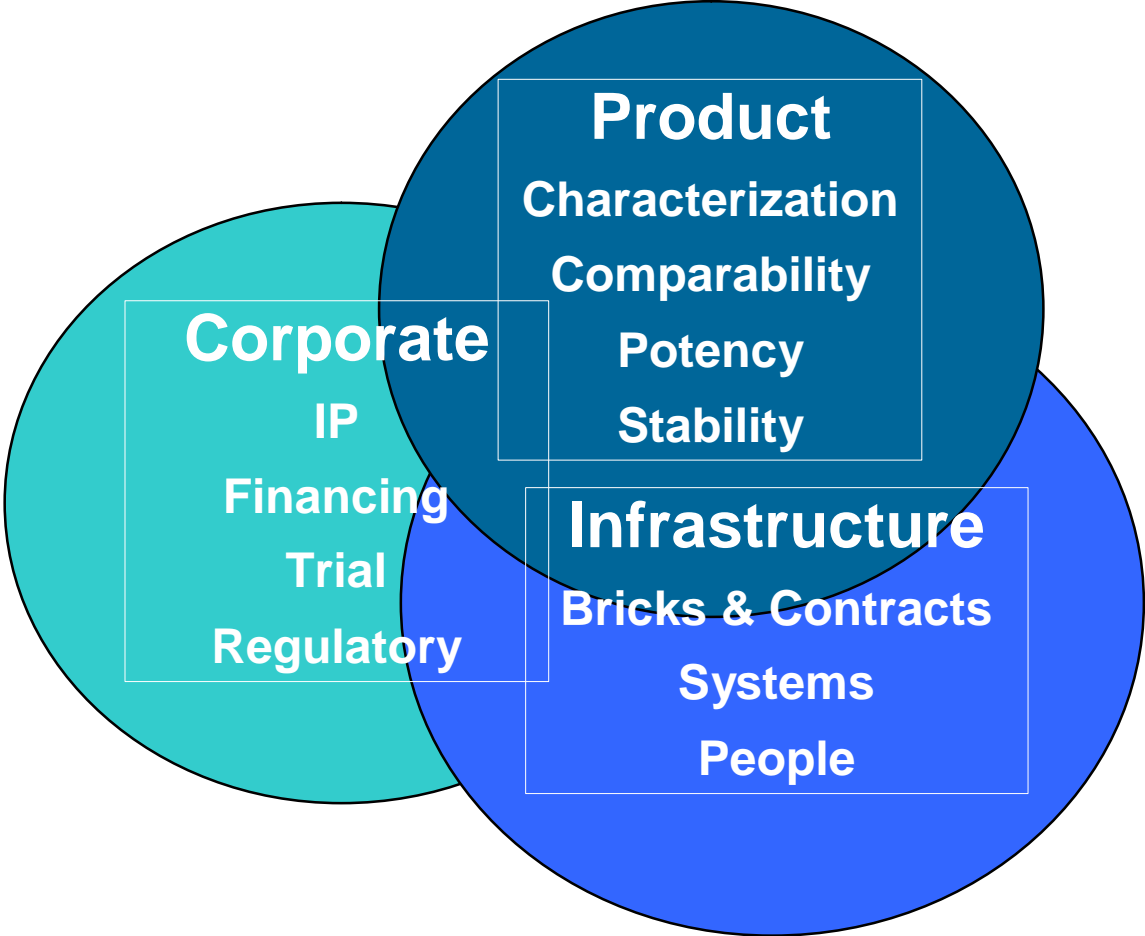
Cell Therapy Commercialization: Gaps



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Cell Therapy Commercialization: Integration



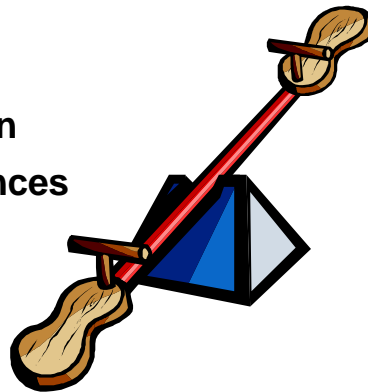
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Successful Commercialization Requires Integrated Solutions

§ Integrated strategy balances:

Long-range vision
Direct consequences
Team focus
Unique solutions



Short-term realities
Indirect impact
Inter-team & inter-discipline collaboration
Integrated solutions across multiple gaps

- Integrated strategy implements solutions that address all (as many as possible) potential implications of each gap not just those directly related

(e.g., comparability is a technical, manufacturing, financial, quality, and regulatory issue)

Make vs Buy



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First: Know Your Product & Process

- § Process may define product
- § Process may be the product
- § Product & process are key to define:
 - Regulatory strategy
 - Development strategy
 - Path to market
 - ü Time
 - ü Financing needs: When and how much
 - ü Investor ROI

“Make vs. Buy” Considerations

§ Infrastructure = Overhead = \$ & time & distraction

- Facility & Equipment
 - ü Initial set-up/design/construction/validation
 - ü Ongoing OPEX, EM, calibration, maintenance, licenses
 - ü Can represent >40% of COGS in Phase I/II trials
- Quality Systems & Documentation
 - ü >2,500 hours for basic policies, systems & procedures
- People
 - ü Direct labor (R&D scientists, mat. control; manufacturing; QC; QA; facilities)
 - ü Indirect labor (Management; purchasing/accounting; QA; regulatory; HR; legal; IT)

“Buy” Benefits - The CMO Advantage

- § Experienced staff who know how to do it
- § Leverage existing infrastructure to drive down cost
 - Validated facilities & equipment
 - Quality systems & operating procedures
 - Regulatory
 - OPEX
- § Campaign - manufacture only when needed
- § Research > Clinical Trial > Commercialization
 - Faster route
 - Linear regulatory path
 - Best ROI

Selecting a CMO



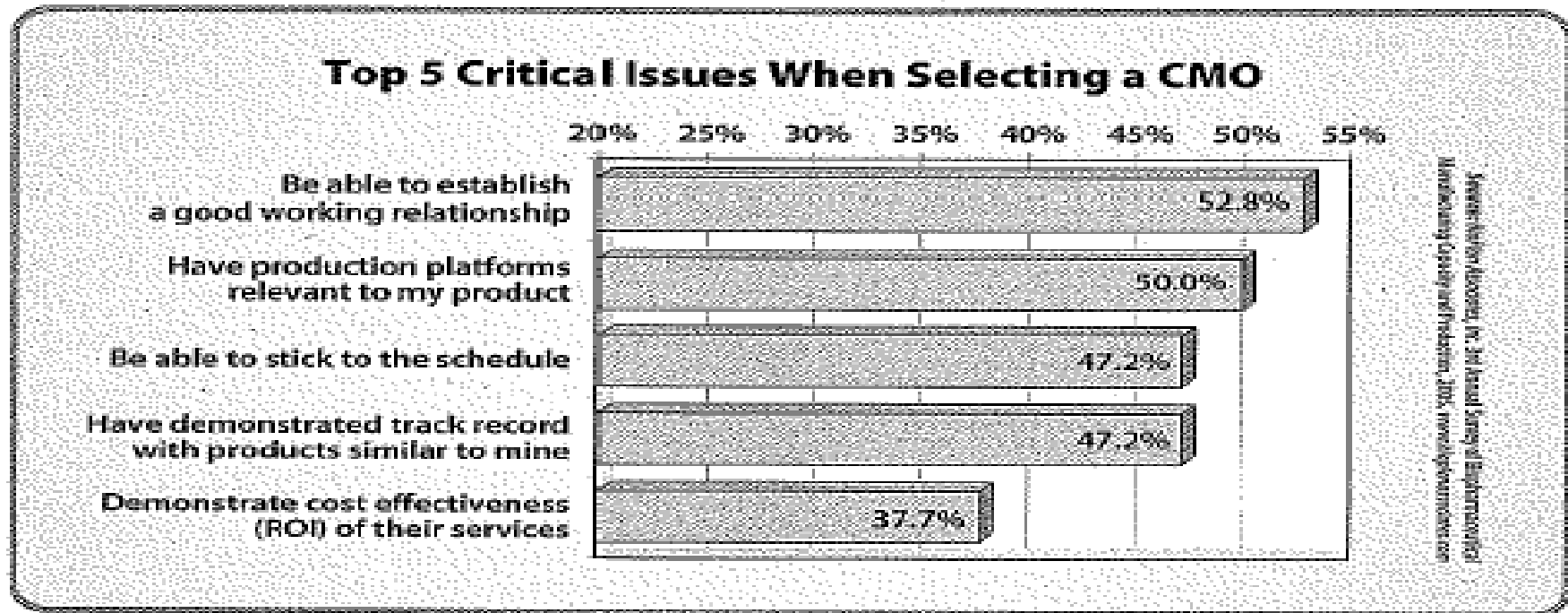
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CMO Selection Prerequisites

- § Honest assessment of what you don't have (and have)
- § Define project
 - Objective(s) – end goal(s)
 - Scope of work
 - Schedule
 - Financial parameters (constraints)
- § Define selection process & criterion

CMO Selection Criteria: Top 5 Issues

ProcessStats: Survey DataPoints



Bioprocess International, February 2007

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Selecting a CMO: It's All About the C's

- 1. Collaboration**
- 2. Capacity/Capability**
- 3. Commitment**
- 4. Competence**
- 5. Cost**

(Compliance is critical but assumed)

(Control is an issue influencing “make vs buy” but not as much “which CMO”)

Genetic Engineering News, October 1, 2006; *Bioprocess International*, February 2007

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After the Selection: contracting

§ Contract must balance

- ü Risk sharing v one-sided burden
- ü Over v under/marginal compensation
- ü Reasonable timelines v unrealistic expectations
- ü Flexibility in terms v reliable revenue stream
- ü Liability
- ü Deliverables
- ü Ability to hold to milestones/deliverable/payment schedules vs flexibility to amend to reflect reality

Overall Philosophy = Teamwork

- § Tight, collaborative project management
 - Define realistic expectations, timelines & deliverables
 - Document and track progression and changes
 - Mechanism for change
- § Know the Product, Process and Overall Project
 - Situational awareness for all elements
- § Communicate frequently
- § “Expect the unexpected”
 - Heurism! - Learn & design from experience

Teamwork = Success



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Execution is a Partnership

- § Clear management team and command
 - Regular and *ad hoc* meetings of management team(s)
- § Active project management
 - Both sides
- § Frequent communication
 - Establishing and regular review of progress against goals/milestones
 - Free & honest information exchange
 - Mutual recognition of respective expertise
 - Creation of an environment of collaboration (solutions not blame)
- § Adjustments in writing (Program Amendments)

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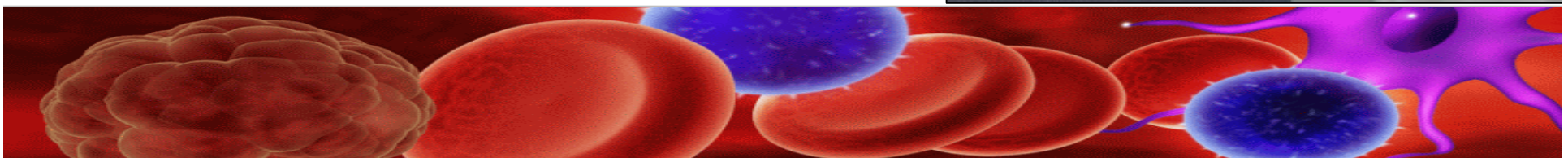
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