About the Alliance for Regenerative Medicine

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organisation dedicated to realizing the promise of advanced therapy medicinal products (ATMPs). ARM promotes legislative, regulatory and reimbursement initiatives in Europe and internationally to advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-based therapies. Early products to market have demonstrated profound, durable and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing ATMPs. In its 11-year history, ARM has become the global voice of the sector, representing the interests of 370+ members worldwide and 70+ members across 15 European countries, including small and large companies, academic research institutions, major medical centres and patient groups.

POSITION TITLE:

Director, European Regulatory – this is an exciting opportunity for a consultant to step into this role, evolving ARM's regulatory strategy consistent with its policy, political and advocacy goals in Europe.

COMPENSATION:

Based on experience. Position is approx. 30 hours per week, with some intra-European travel required along with occasional travel to the U.S.

LOCATION:

Preference for position to be based in Brussels, Belgium, but will consider qualified candidates in other European countries.

POSITION OVERVIEW:

The Director, European Regulatory will report to the Senior Vice President of Global Public Affairs and collaborate with her to develop, drive and execute ARM's regulatory affairs strategy in Europe. This role will lead the European Regulatory Affairs Committee and work closely with European and US colleagues.

RESPONSIBILITIES:

- Advance ARM's regulatory policy positions among key European stakeholders, including the European Commission, The European Medicines Agency and the EMA's Committee for Advanced Therapies, among others.
- Reinforce ARM as the global – and European – voice of the cell & gene therapy sector, ensuring stakeholders reach out to ARM for all

regulatory-related guidance and inquiries in the ATMP sector.

- Actively and strategically manage ARM's European Regulatory Affairs Committee, including: lead ARM's response to public consultations that focus on ATMPs, draft/edit position papers, partner with Committee co-chairs on goal achievement and meeting agendas, and regularly interact with members.
- Engage with the European Medicines Agency and its relevant committees, as well as country-specific regulatory bodies to support and advance ARM's regulatory policy positions.
- Partner with US Regulatory counterpart as well as the European Directors of Public Affairs and Market Access & Value, and the Director of Public Affairs (global media) to ensure the consistent execution of ARM's integrated European public affairs strategy.
- Prep SVP Global Public Affairs, ARM CEO and colleagues in advance of regulatory meetings with key European stakeholders.
- Join Director of European Government Relations & Advocacy, as needed, at policymaker meetings to advance regulatory policy.
- Draft policy positions and papers, briefing documents, reports, etc.

SKILLS & EXPERIENCE:

- 15+ years' experience as an effective Brussels-focused healthcare and/or biotech regulatory specialist. Previous in-house, corporate experience is a strong plus.
- Must have 5+ years' experience in public affairs and/or government relations, having executed integrated pan-European strategic public affairs campaigns.
- Demonstrated ability to strategically assess developing regulatory opportunities and risks and counsel ARM colleagues in real-time.
- Adept at translating complex healthcare terminology into easily understandable information for policymakers.
- Demonstrated experience effectively engaging with relevant European regulatory stakeholders in Brussels, at the pan-European and individual country levels.
- Ability/desire to regularly work early evening hours to collaborate with US colleagues.
- Experience working for a US-based corporation or organization is a plus.
- Seeking energetic, go-getter – accomplished in seeing around corners & making things happen. Team player who lives and breathes collaboration.
- Exhibits calm under pressure and when working against deadlines.
- Demonstrates highly professional demeanor and excellent inter-personal skills; experienced working with policymakers.
- Experience partnering with external vendors, including public affairs agencies.
- Fluency in English required. Fluency in German or French a plus.
- Exceptional written and verbal communication skills.
- BS/BA required; MS/MA/MBA preferred.

Interested applicants should send a resume and cover letter to: Rashida

Dujue-Jackson @ rdujue-jackson@alliancerm.org