Justin Michael

REGULATORY AFFAIRS COORDINATOR

CONTACT

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SKILLS

- Regulatory Affairs
- Clinical Trials
- Real-World Evidence
- Project Management
- Analytical Mindset
- Structured

LANGUAGES

- English
- Arabic
- French
- German

HOBBIES

Reading Books

Sport

REFERRAL

Upon your request

EDUCATION

MSc. In Pharmaceutical Science
University of Southern California
Oct 2015 - Jan 2018

BSc in Pharmacy (5 years)
Northeastern University

SUMMARY

Highly structured, problem solving, motivated, and responsible certified pharmacist in Denmark. Recently, specilaised in regulatory science graduating with master in Pharmaceutical Science from University of Copenhagen 2018. Offering broad experience within regulatory affairs, clinical trials, labelling and real-world evidence combined with project management skills. Work both independently and in multidisciplinary team with ability to communicate in a cross-cultural organization.

EXPERIENCE

Regulatory Affairs Coordinator
Margo Surgical LLC *Jul 2019 - Present*

- Set regulatory strategy for changes implementation worldwide
- Registration worldwide
- Follow-up with guidance and regulation worldwide

Regulatory Affiars and Real-world Evidence Data analyst
Davin Cooper LLC *Aug 2017 - Jan 2018*

- Analyzed label, guidance, regulation, and approval decisions in EU-EMA and US-FDA to identify trends and gaps or alignment in their current regulatory strategy and to explore new approaches toward a new regulatory strategy that will not only influence EMA and FDA regulations but also regulations worldwide.
- Interpreted regulatory guidance and clinical trial study design for both EU-EMA and US-FDA to investigate a new approach in developing clinical trials that generate effective clinical outcomes that meet patient needs.
- Responsible for questions received from EMA, FDA, and Switzerland during NDA assessment and for the phase 3a program.

LABELLING

- Identified trends among labels (CCDS, ENDS), prescription leaflets, and patient information documents.
- Organized and prepared successful workshops for professionals discussing label changes.
- Prepared non-EU label documents (ENDS).

CLINICAL TRIALS

- Analyzed EMA and FDA approval decisions that were based on submitted clinical trials to identify trends and gaps or alignment in their clinical trial development approach.
- Proposed alternative clinical study design for clinical drug development of fixed-dose combination products that are effective and aligned with patient needs in real-world clinical practice.

REAL-WORLD EVIDENCE

- Collaborated with Danish community pharmacists to collect for first time patient-reported outcomes (PROs) in real-world clinical practice that is to compare the PROs in clinical practice versus PROs collected in controlled clinical trials.
- Designed and developed a patient-based questionnaire to collect real-world PROs that are distributed to the pharmacists and trained in how to use the questionnaire and communicate with patients.

Boston, Massachusetts
Aug 2008 - Sep 2014

- Ongoing voluntarily collecting and analyzing real-world evidence (RWE) represented by PROs on fixed-dose combination product called (Xultophy) in collaboration with the University of Copenhagen and Danish community pharmacies network.