

To: Sunil Dhawan[]
From: Sunny Balwani
Sent: Wed 11/19/2014 11:10:42 PM
Importance: Normal
Subject: RE: Lab Director
Received: Wed 11/19/2014 11:10:41 PM

this is all we need.

we have all paperwork in place and I will have one of the couriers bring it by your office tomorrow am for your signature.

thanks for this. I appreciate it.

From: Sunil Dhawan [mailto:]
Sent: Wednesday, November 19, 2014 11:02 AM
To: Sunny Balwani
Subject: Re: Lab Director

we have a certificate for the practice and I am the lab director- is that ok?

Sunil S. Dhawan, MD

Center for Dermatology, Inc.

Center for Dermatology Clinical Research, Inc.
-Office-MWF

-TTh

-Cell

- email

[www. centerforderm.com](http://www.centerforderm.com)- main practice site

www.ctr4derm.com- clinical research site

On Tuesday, November 18, 2014 2:22 PM, Sunny Balwani <sbalwani@theranos.com> wrote:

Thanks for this.

I assume you don't have the CLIA licensing. If that's correct then first thing would be to file your paperwork for this which my lawyers can do. We have a great team which is very experienced. If ok, I will ask Brad Arington, our senior Regulatory affairs council to reach out to you and get this going. As soon as all this is done, we can put your name on our company's certificate. In the meantime, I can send you a short contract to take care of the business side of this.

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Sunny.

----- Forwarded message -----

From: **Sunil Dhawan** < >
Date: Tue, Nov 18, 2014 at 12:43 PM
Subject: Re: Lab Director
To: Sunny Balwani <sunny@>

Sunny,

I can do this- what is next step?

Sunil Dhawan

Sunil S. Dhawan, MD

Center for Dermatology, Inc.

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On Friday, November 14, 2014 8:04 PM, Sunny Balwani <sunny@> > wrote:

Sunil.

Thanks for talking my call.

The time commitment is very minimal. This will be mostly an on call consulting role and I am extremely confident that it wont interfere with your work or with your family life. I am attaching the requirements here. Please let me know if you will be able to do this or perhaps someone else you know. This will be 1-3 months

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US-REPORTS-0008350

role.

Thanks in advance.

With my best regards,

Sunny Balwani

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For an MD to serve as a lab director, the California statute (1209(a)) includes a duly licensed physician and surgeon. To practice medicine in California, the M.D. would have to be licensed in California. From 1209(a): "laboratory director" means **any**

person who is a duly licensed physician and surgeon...

An MD also has to meet the requirements under CLIA which are provided in Section 493.1443. For MDs there are the following alternatives:

1. Licensed to practice medicine in the State in which the laboratory is located and certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification
2. Licensed to practice medicine in the State in which the laboratory is located and Either: (i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine – see additional information from the Interpretive Guidelines below on Residency Training); or (ii) Have at least 2 years of experience directing or supervising high complexity testing (see additional information from the Interpretive Guidelines on Training and Experience below)

Additional information:

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Interpretive Guidelines "Residency Training" --

The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phase of the total process (i.e., preanalytic, analytic and postanalytic), as well as, general laboratory systems, facility administration, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing.

Interpretive Guidelines: "Training and Experience"

The type of experience required under this regulation is clinical in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is unacceptable to meet the requirement for laboratory training or experience.

The laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1445.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.

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