

The Art and Science of Dossier Presentation: The Medicines Evaluation & Research (ME&R) Perspective

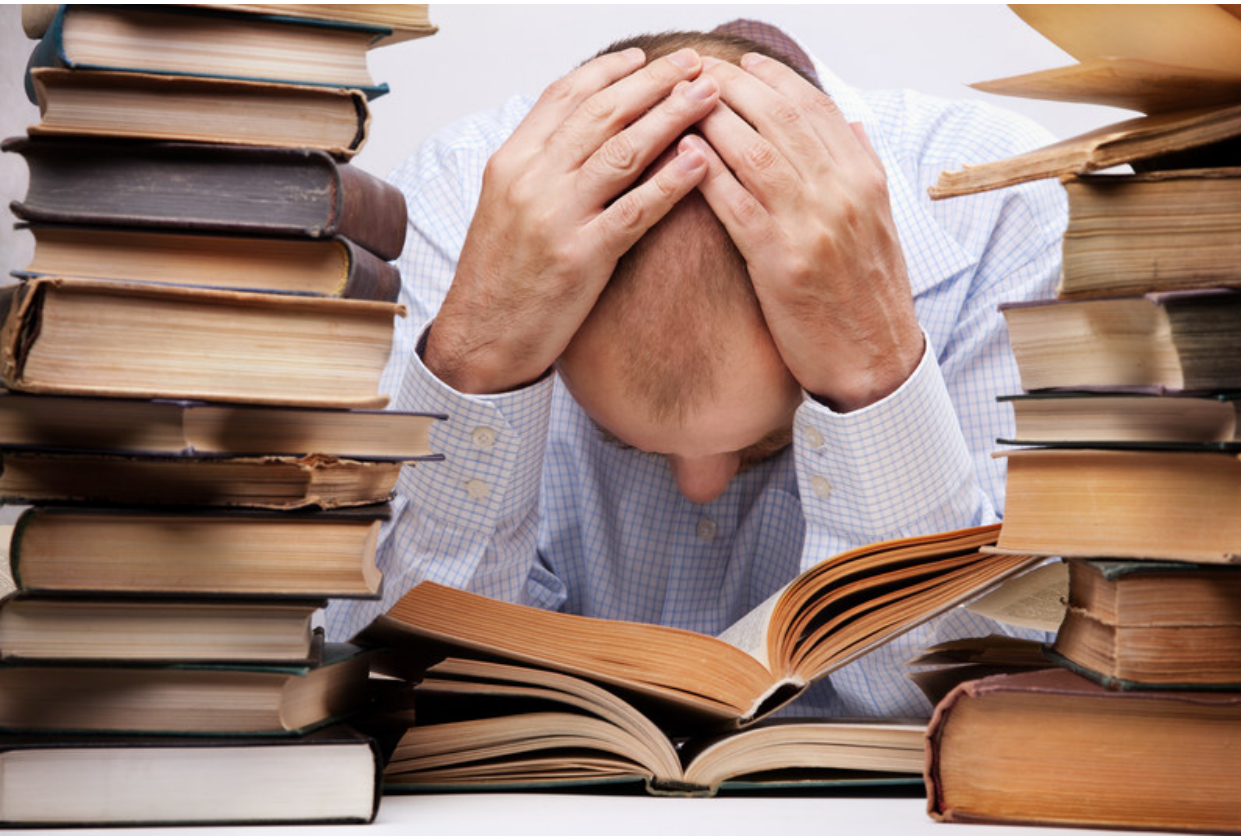
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Greetings from the ME&R.



This presentation is not intended to point fingers at the applicant.



Science is often hard to read and differs from reading stories in newspapers, magazines and novels.

DO WE AGREE?

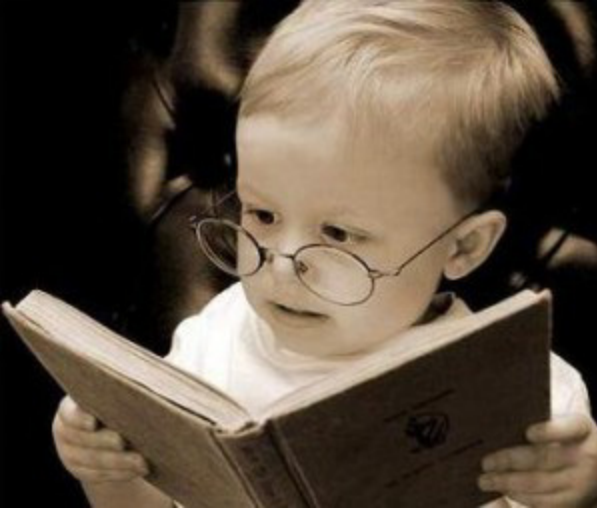


What is the evaluator's expectation?
“Comments received from your own colleagues”
who assisted with review of applications
in the backlog.

“We now appreciate that we do not understand how
the evaluators go about the evaluation process”.



Missing info: What are the dangers of missing logical gaps?

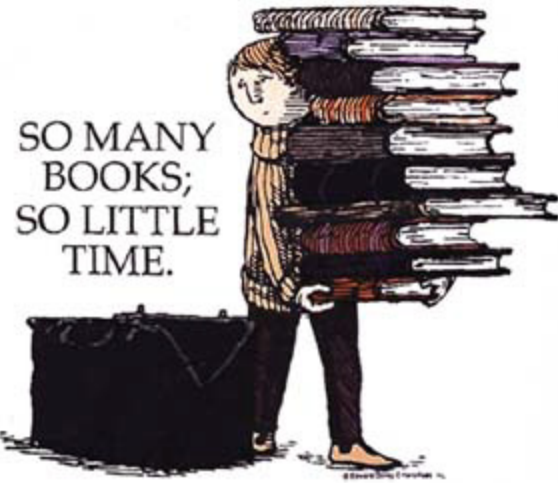


*I can't deal
with this
right now. I
just want to
go to sleep
and wake up
next year.*

The inexperienced/junior evaluator is
often left in the dark



The semi-experienced evaluator is most likely to draw upon some of their knowledge.



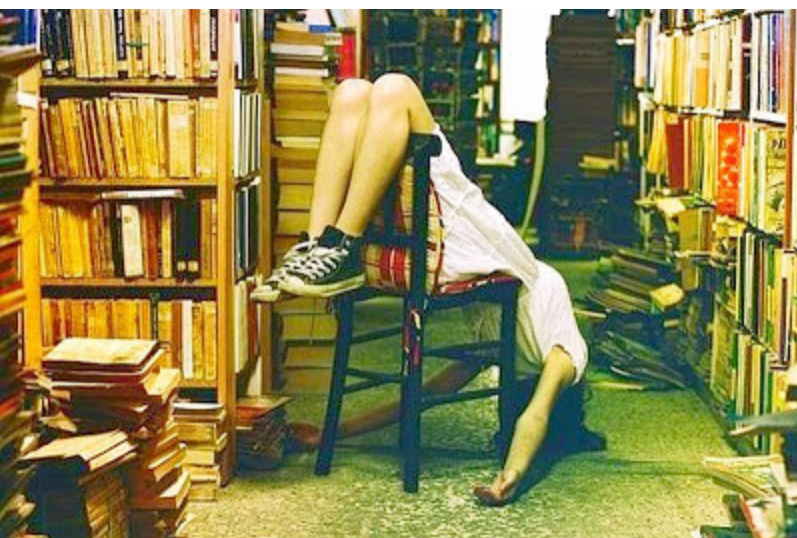
Common queries from applicants:

Why did I get 2 different recommendations for the same application?



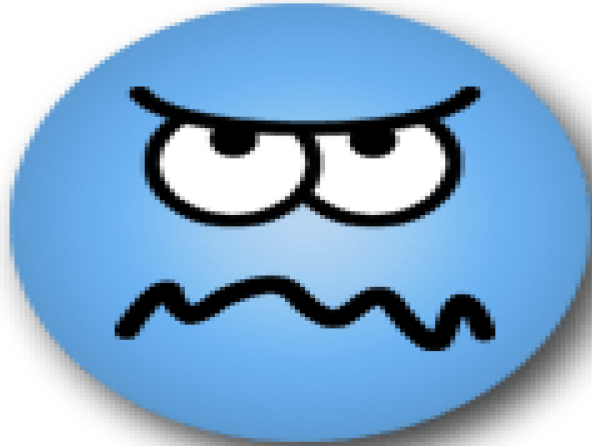
**Why are first recommendations
“excessive/lengthy”?
Is it really necessary?**

Be on target.



Are we as the Regulator justified to reject applications? Is the Regulator being unreasonable?

Our basis for rejecting of applications.



**Why did I get 2 different recommendations
for the same application?**

do

what

you

love

love

what

you

do



THANK YOU



GOOD BYE